# Understanding overweight and obesity: The end of average

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

## Summary

### ID

NL-OMON53868

**Source**
ToetsingOnline

**Brief title**
Understanding Overweight and Obesity

### Condition

- Other condition

**Synonym**
corpulence; adiposity

**Health condition**

Obesitas, overgewicht

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** NWO Talent Programme - VICI - SSH

## Intervention

**Keyword:** Network approach, Obesity, Overweight, Personalized interventions

## Outcome measures

### Primary outcome

At baseline, a comprehensive set of variables will be assessed, all of which have been associated with overweight and obesity in previous empirical studies. These include biomedical variables (e.g., ghrelin and leptin), psychological variables (e.g., depressive symptoms), person characteristics (e.g., age), environmental variables (e.g., neighbourhood safety) and behavioural variables (e.g., usual eating habits). It In addition, we will collect time-series data on (un)healthy eating and physical (in)activity, and predictors of these behaviours (e.g., emotions) in daily life, both at baseline and after intervention.

### Secondary outcome

Not applicable

# Study description

### Background summary

Overweight is the largest and most prevalent modifiable risk factor for health problems, and significantly contributes to healthcare costs. Researchers generally agree that overweight is multifactorially determined, including biomedical, behavioral, environmental, and psychological mechanisms. There is empirical support for each of these mechanisms, but often evidence is not

consistent across studies, effect sizes are modest at best, and variability on outcome-measures across participants in a study is often large. This suggests that contributing factors to overweight likely differ across people. Similarly, treatments for overweight are, on average, only modestly effective and individual variability in weight-loss-response to treatment is large.

## Study objective

This project therefore adopts an urgently needed comprehensive individualized approach. We characterize each participant in a large sample of individuals varying in bodyweight by their own baseline comprehensive profile, including person characteristics, biological, psychological, environmental, and behavioral variables. Next, we investigate how baseline comprehensive individual profiles cluster in a meaningful way, and relate to bodyweight at baseline, post-treatment, and follow-up. We also test if results for weight change are moderated by treatment-condition: Intensive Lifestyle Intervention (ILI) versus lifestyle-information control group.
Moreover, we investigate how these individual profiles translate to behavior in daily life. We collect time-series data on (un)healthy eating and physical (in)activity, and predictors of these behaviors (e.g., emotions, stress) in daily life during three weeks at baseline and three weeks post-treatment. Based on these time-series data, we estimate daily lifestyle networks per individual (baseline/post-treatment), and relate these to the comprehensive individual profiles. Moreover, we investigate how these daily lifestyle networks relate to bodyweight, and change over time, dependent on treatment condition. We hypothesize that*after ILI and mostly with more weight loss*healthy behaviors increase, and predictors link with healthy behaviors more frequently in these networks. The proposed research puts the individual center stage, paving the way for personalized interventions.

## Study design

This study, will use an open study design with 3 parallel groups.

## Intervention

The participants with overweight and obesity are randomly assigned to either an intensive lifestyle intervention or a lifestyle-information control group.

## Study burden and risks

All participants need to take part in a measurement day at our centre, during which a BodPod measurement is performed, three blood samples are obtained, and a physical fitness test is performed. In addition, they will fill out a set of standardized questionnaires via Qualtrics and will take part in two 3-week periods of ecological momentary assessment (EMA) via smartphone and wear a

provided activity tracker. The EMA-protocol will prompt participants 8 times a day to answer questions on their smartphone about variables such as food craving, emotions and stress.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)

### Inclusion criteria

1. Is informed and has been given a minimum of 7 days to consider participation and has given informed consent in writing; 2. Is male or female and in the age range between 18 and 65 years (inclusive); 3. Has a body mass index (BMI) in one of the following ranges - Healthy weight: >=18.5 and <=25.0 kg/m2; - Overweight: >25.0 and <=30.0 kg/m2; - Obese: >30.0 kg/m2 4. Is a fluent Dutch speaker. 5. Has been weight stable (±3 kg) for the past three months.

### Exclusion criteria

1. Female participant who is pregnant;
2. Is currently in specialized treatment for overweight/obesity;
3. Is currently in specialized treatment for a mental disorder;
4. Has had gastric surgery;
5. Is taking medication for chronic conditions such as diabetes, pulmonary disease, and heart and vascular disease that interfere with the measurements of the current study.
6. Is not capable of taking part in all measurements;
7. Is physically disabled.

## Study design

### Design

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

**Primary purpose:** Prevention

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 08-01-2024 |
| Enrollment: | 600 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 21-08-2023 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

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| Approved WMO Date: | 09-11-2023 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | NL81710.068.23 |