# Personalised combined lifestyle intervention

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22186

**Source**
Nationaal Trial Register

**Brief title**
SLIMMER-Personalised (hPoC: human proof of concept study)

**Health condition**

Obesity

### Sponsors and support

**Primary sponsor:** TNO in collaboration with GGD-NOG (owner of SLIMMER)
**Source(s) of monetary or material Support:** TNO

### Intervention

### Outcome measures

**Primary outcome**

Compliance/adherence. Evaluated by:
• User experiences (qualitative aspects including effort, maintenance, and appreciation) at the end of the intervention (month 6);
• Improved lifestyle behavior (subjective compliance as well as actual compliance measured by physical activity and dietary intake) (after the intervention at t=6 months compared to

lifestyle behavior before the start of the intervention t=-1 month).

### Secondary outcome

• What is the effect of extended personalization to a combined lifestyle intervention program on health status? Measured by:
o Well-being (subjective, using the EQ-5 questionnaire at month: t=-1 (before start intervention), t=3 (halfway intervention), and t=6 (end of the intervention)
o Anthropometrics (weight, BMI, waist circumference, etc.) before and after the intervention (t=-1 month and t=6 months)
o Metabolic resilience before the intervention (month -1 (one month before the start)) (calculate a composite marker in response to the PhenFlex test based on dynamic measurements of glucose, insulin, NEFA, TG, and cholesterol) of blood collected at t=0, 30, 60 120, and 240 minutes after start consumption of PhenFlex drink and after the six months intervention (t=6 months)
o HbA1C (fasting) before and after the intervention (t=-1 month and t=6 months)
o IFN-γ, leptin, high-sensitive C-reactive protein (hsCRP), adiponectin, IL-6, MPO, and IP-10 to calculate an inflammatory score of blood collected at t=0, 30, 60 120, and 240 minutes after start consumption of PhenFlex drink before and after the intervention (t=-1 month and t=6 months).

## Study description

### Background summary

Rationale: Obesity and type 2 diabetes have become a global health concern. A healthier lifestyle can remit or reverse type 2 diabetes, which could be more effective than medication, e.g. metformin. Furthermore, a healthy lifestyle can improve low-grade inflammation and improve the composition of the microbiome. Yet, achieving and containing a healthier lifestyle behavior is difficult. Personalization, i.e. tailoring to an individual’s needs and preferences, is an important factor for achieving sustainable healthy lifestyle habits. The “SLIMMER” combined dietary and exercise program is one of the effective interventions in the Netherlands, that has been included in the basic package of the health care provider.
Objective: We aim to assess 1) whether subjects will show better compliance when the lifestyle intervention is more personalized (using TNO tools and techniques) compared to the regular lifestyle intervention, and 2) the effectiveness of the combined dietary and physical activity intervention on metabolism and inflammatory status. Furthermore, we aim to explore the possible effects of a combined lifestyle intervention on mycobiome and microbiome composition and functional activity in the intestine. We hypothesize that better compliance may eventually lead to more effective lifestyle behavior changes.
Study design: The study will be designed as a parallel, open-label, intervention study. The intervention in this study consists of two arms: one intervention group (n=60) and one control group (n=60).
Study population: Males and females, aged 18-70 years, with overweight or obesity, who are

referred by their GP to, and meet the inclusion criteria of the SLIMMER program.
Intervention: All participants will be followed during the first 6 months of the SLIMMER program. In participants in the control group, fasting blood will be drawn at the beginning and end of the study. Participants in the intervention group receive the same care as the control group, but with personalization tools on top of it. These items include: more personalized dietary and exercise advice based on a mixed meal challenge (PhenFlex), 360 degrees diagnosis, self-monitoring, personalized digital behavioral support, intermediate feedback based on lab values and behavior, and blended care. Therefore measurements will be conducted before the start of the study; one month before the start of the intervention (t=-1 months) and after the six months of intervention (end, t=6 months).
Main study parameters/endpoints: To examine the effects of extended personalization to a lifestyle intervention program difference on compliance and physiological responses. The main objective of this study is to achieve better compliance to the lifestyle intervention program, measured by subjective compliance (participants score their degree of compliance with the given lifestyle advice every 3 months and objective compliance (based on the 'Eetscore' and amount of physical activity, and presence at sessions). Participants will also rate the effort and overall program. The PhenFlex test will be used as a metabolic stress test to examine changes in inflammatory status due to a lifestyle intervention program. To examine the effect of the intervention, subjects will undergo a PhenFlex challenge test before and after the intervention. Subjects will drink the PhenFlex drink in fasted condition, and blood will be collected at t=0, 30, 60 120, and 240 minutes after the start of consumption. In collected blood, metabolic and inflammatory markers will be measured. Composite biomarkers, taking multiple markers and timepoints together, will help us to monitor changes in metabolic and inflammatory response due to the SLIMMER-Personalised intervention.
Nature and extent of the burden and risks associated with participation, benefit, and group relatedness: Participants follow the SLIMMER program. For study purposes, at the beginning and at the end of the intervention, subjects will visit TNO for a test day. Blood samples will be drawn to examine the metabolic response to the PhenFlex. A fecal sample swab will be collected in the week before each test. During the study, some questionnaires need to be completed. During the combined lifestyle intervention subjects will participate in multiple group exercise- and coaching sessions and some individual sessions. Subjects will be monitored continuously by physiotherapists, dieticians, lifestyle coaches, and general practitioners (assistant). No risk or real burden is of concern in this study.

## Study objective

1. Personalised tools and technologies help to stimulate an increased compliance to a healthy lifestyle in people with overweight and/or obesity and who are cardio-metabolically compromised. Increased compliance may (eventually) lead to a more effective intervention or longer maintenance of a healthy lifestyle;
2. A combined lifestyle intervention can reduce low-grade inflammation in people with overweight and/or obesity and who are cardio-metabolically compromised.
3. A combined lifestyle intervention has positive effects on gut health, measured by composition and functional activity of the micro- and mycobiome

## Study design

Before (t= -1 month) and after the six months intervention (t=6 months) test days will be conducted (see primary and secondary outcomes).
At test days an energy rich drink will be consumed, also called the 'PhenFlex challenge test'. Before and at fixed time points after consumption of the drink blood will be drawn (at t=0, 30, 60, 120 and 240 minutes). This test will be conducted before and after the intervention period to examine the phenotypic flexibility of a subject.

**Intervention**

The study will be designed as a, parallel, open label, intervention study. The intervention in this study consists of two arms: one intervention group and one control group. Participating practices will participate either as an ‘intervention practice’ or ‘control practice. Hence, all participants in a particular health care practice are either intervention group, or control group. This will be done to prevent knowledge spill-over, i.e. to prevent health care providers in the ‘intervention’ group from using their knowledge for control participants.
The participants of the study will be individuals with obesity or overweight and an increased risk for CVD, that were referred by their general practitioner (GP) to follow the two-year combined lifestyle intervention, the SLIMMER program.

For this study, participants will be followed during the first six months of the SLIMMER program.
- The control group will include participants who follow the regular SLIMMER program.
- The intervention group will include participants who follow the regular SLIMMER program and, on top of the regular program, a more personalized intake and personalization feedback moments throughout the program will be provided.

The SLIMMER program is a combined dietary and physical activity lifestyle intervention, which is implemented in Dutch primary healthcare. Participants can get referred to this program by their general practitioner.
Participants of the regular SLIMMER program will be used as a control group. While the SLIMMER program lasts two years, in our study, we will follow the participants only during the first six months of the program. The SLIMMER program consists of an individual intake, followed by an intensive group session program of six months, which is focused on nutrition (supervised by a dietician), and physical activity (supervised by a physiotherapist). After the six months intensive period, a consolidation period takes place, in which individuals participate in local physical activity programs, and participate in meetings regarding lifestyle behavior maintenance.

# Contacts

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# Eligibility criteria

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria in addition to the above:
• Physically able to participate in a lifestyle intervention program;
• Motivated to join lifestyle program.
• Able to use online technology on a tablet or a PC/laptop which has good access to the internet;
• In possession of a Smartphone running on a recent version of iOS or Android;
• Willing to comply with all study procedures;
• Proficient in the Dutch language (speaking and reading).

## Exclusion criteria

• Exclusion criteria from the SLIMMER programme:
1) Behavioural problems that obstruct group sessions
2) Cognitive impairment (IQ < 80);
3) Psychopathology, that requires a different treatment
4) Having an underlying cause of obesity that can be treated;
5) incompetent to act for oneself, without consent of the legal representative.
• Participation in another regular vigorous exercise program (sporting at least 3 times a week) and/or diet program
• Participation in any clinical trial including administration of substances up to 90 days before Day 01 of this study
• Severe cardiovascular disease (this also includes history of cardiac dysrhythmia), unless GP gives agreement
• Not being able to attend 80% of the planned group- and individual sessions;
• Planned surgery during the entire study period
• Pregnant or lactating women
• Using on a regular base: anti-inflammatory drugs (NSAID’s), corticosteroids (including topical and inhalation corticosteroids), TNF-alpha blockers, and salicylates (e.g. ascal)
• Having a chronic inflammatory disease, including asthma, rheumatic fever, IBD, COPD
• Other bowel diseases, including Chron’s disease and Colitis Ulcerosa.

• Alcohol consumption > 21 units/week
• Recent blood donation (<1 month prior to the start of the study)
• Not willing to give up blood donation during the study
• Personnel of TNO Healthy Living, their partner and their first and second degree relatives

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 11-12-2020 |
| Enrollment: | 120 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** No

# Ethics review

Positive opinion

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| Date: | 11-12-2020 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL9145 |
| Other | METC Brabant (P2048); NL75482.028.20 : P2048 |

# Study results