The effect of extended personalisation components to a combined lifestyle intervention program.

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Objective: We aim to assess 1) whether subjects will show better compliance when the lifestyle intervention is more personalised (using TNO tools and techniques) compared to the regular lifestyle intervention, and 2) the effectiveness of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51873

Source
ToetsingOnline

Brief title
Personalised combined lifestyle intervention (Slimmer-Personalised)

Condition

- Other condition

Synonym
fatness, obesity

Health condition

overgewicht en obesitas

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO;via VWS

Intervention

Keyword: dietary advices, lifestyle intervention, obesity, overweight

Outcome measures

Primary outcome

Main study parameters/endpoints: To examine the effects on 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 grade the effort, maintenance and appreciation of the intervention program) and objective compliance (based on the *Eetscore* and amount of physical activity, and presence at sessions).

Secondary outcome

The PhenFlex test will be used as a metabolic stress test to examine changes in inflammatory status due to a lifestyle intervention program.
With a health patch some physical variables will be measured (ECG, bio-impedance and accelerometry).

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 behaviour 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.

The extension of the research period corresponds to the duration of the regular SLIMMER programme. We would like to evaluate the effectiveness of the entire intervention and therefore also examine the effects in the long term.

Study objective

Objective: We aim to assess 1) whether subjects will show better compliance when the lifestyle intervention is more personalised (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 in the intestine. We hypothesize that better compliance may eventually lead to more effective life style behavior change.

The long-term findings and possible differences in compliance as a result of the personalisation are also interesting data for publication.

Study design

Study design: The study will be designed as a randomized, 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).
tests will be conducted before and after the intensive first six months at month 0 and month 6.

Data of various questionnaires at 12 and 24 months of the study will be collected. Physical data of these timepoints will be requested from thelifestyle coach.

Intervention

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

personalisation 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 behavioural support, intermediate feedback based on lab values and behaviour, and blended care.

Study burden and risks

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, metabolic stress test. 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 the general practitioners (assistant). No risk or real burden is of concern in this study.

Contacts

Public
TNO

Utrechtseweg 48
Zeist 3704 HE
NL
Scientific
TNO

Utrechtseweg 48
Zeist 3704 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Men and women aged 18-70 years
• BMI > 30 kg/m2, or
• BMI > 25 kg/m2 with an increased risk of cardiovascular diseases and/or type 2 diabetes, based on the Dutch primary care guidelines cardiovascular risk management (CVRM), obesity and diabetes.
• Increased waist circumference (women > 80 cm and men > 92 cm);
• Little physical activity and suboptimal diet (room for improvement);
• Physically able to participate in a lifestyle intervention program;
• Motivated to join lifestyle program.
• Able to use online technology on a tablet and 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

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Exclusion criteria from the SLIMMER program:
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 the 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
• Preferably not use anti-inflammatory drugs (NSAID*s), corticosteroids (including topical and inhalation corticosteroids), TNF-alpha blockers on a regular base

• Other bowel diseases, including Chron*s disease and Colitis Ulcerosa.
• Alcohol consumption > 21 units/week
• Recent blood donation (<1 month before 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

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-03-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	26-07-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	29-11-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-09-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL75482.028.20
Other	NL9145