

# Improving cardiometabolic health through nudging dietary behaviours and promoting physical activity in adults with low socioeconomic position: implementation and evaluation of the SUPREME NUDGE trial

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To evaluate the effect of environmental nudges and pricing strategies in the supermarket, as well as a mHealth (mobile health) physical activity intervention, primary on the dietary intake.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON55132

### Source

ToetsingOnline

### Brief title

SUPREME NUDGE

### Condition

- Other condition

### Synonym

Cardiovascular disease; lifestyle diseases

### Health condition

Risicomarkers voor cardiometabole ziekten (lipidenspectrum, HbA1c, bloeddruk en middelomtrek)

## **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** ZonMW, De Hartstichting

## **Intervention**

**Keyword:** Cardiometabolic health, Health behaviour, Nudging, Socioeconomic-position.

## **Outcome measures**

### **Primary outcome**

The primary outcome is adherence to the Dutch dietary guidelines.

### **Secondary outcome**

Secondary outcomes are changes in cardiometabolic outcomes (i.e. HbA1c, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol, total cholesterol (TC), TC/HDL-ratio, triglycerides (TG) and waist circumference), number of steps per day, food purchasing behaviours in the supermarket, habit formation of health behaviours, social cognitive factors in relation to nudges, self-monitoring, action planning, social comparison, self-efficacy and supermarket customer satisfaction over 6 of 12 months compared with a control arm, and acceptance of nudges and technology at 6 or 12 months.

## **Study description**

### **Background summary**

Lifestyle behaviours associated with increased cardiometabolic disease (CMD) risk, such as unhealthy dietary patterns and lack of physical activity, tend to cluster in adults with a low socioeconomic position (SEP), putting them at high risk. Individual interventional approaches aiming to reduce CMD risk show limited effect in populations with low SEP, as they often rely on individual agency. Environmental interventions create opportunities for sustainable behaviour change without much individual agency, by making the healthy choice the easy choice.

## **Study objective**

To evaluate the effect of environmental nudges and pricing strategies in the supermarket, as well as a mHealth (mobile health) physical activity intervention, primary on the dietary intake.

## **Study design**

The trial will be performed according a parallel randomised controlled design with the nudging and pricing interventions implemented on the supermarket level (12 store locations) with cluster-randomisation and the physical activity intervention randomised at the individual level across all clusters. We will determine the effectiveness of a combination of nudging and pricing strategies in the supermarket, with: i) control group receiving no intervention; ii) intervention group receiving supermarket nudges and supermarket pricing strategies. The effectiveness of the mHealth intervention aiming to improve physical activity levels at the individual level will be investigated with: i) control group receiving no intervention; ii) intervention group 1 receiving mobile individualized feedback strategies to improve the number of steps per day.

## **Intervention**

A combination of environmental nudges, such as food product placement or promotion, and pricing interventions in the supermarket, as well as a tailored mHealth physical activity intervention with time- and context specific feedback through text messages. The intervention phase will be 6 or 12 consecutive months (depending on enrolment date) to account for seasonal variation in shopping and physical activity behaviour.

## **Study burden and risks**

Participants will be subjected to four measurement rounds, of which two or three will include minimally-invasive physical examinations and questionnaires (at baseline and after 6 months (and 12 months)), and one will include only questionnaires (at 3 months). The participants conducts the waist circumference measurement at home and collects the blood samples via a finger prick test at

home, collecting four drips for HbA1c and 16 drips for the lipid test. Participants will be asked to download a mobile app and wear their phone as much as possible for the measurement of the number of steps per day. In conclusion, the intervention and measurements do not entail a risk for the participants. The burden consists of the time participants need to invest in the participation and the physical examination at 0, and 6 (and 12) months. The benefit is that participants are informed on their cardiometabolic risk factors, and provided with the possibility to automatically make more healthy lifestyle choices without actively having to change their behaviours.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Aged 30-80 year

- Having low socioeconomic status (lower and secondary education as highest completed level of educational and/or living in a social deprived neighbourhood)
- Do their main household grocery shopping at one of the selected supermarkets (\*50% of weekly groceries purchased at the selected store, and planning on continuing visiting for the next year);

## Exclusion criteria

- Not being able to communicate adequately in the Dutch language

## Study design

### Design

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

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2021
Enrollment:	360
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	06-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	02-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	04-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	15-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-08-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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
Other	Nederlands Trial Register ID NL7064
CCMO	NL69908.029.19