

# SUstainable PREvention of cardioMEtabolic risk through NUDGing hEalth behaviors

No registrations found.

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Positive opinion    |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | -                   |
| <b>Study type</b>            | Interventional      |

## Summary

### ID

NL-OMON20990

### Source

NTR

### Brief title

SUPREME NUDGE

### Health condition

Cardiovascular diseases; cardiometabolic health; type 2 diabetes.

## Sponsors and support

**Primary sponsor:** The SUPREME NUDGE project is carried out by a consortium, coordinated by Amsterdam UMC (Formerly VU University Medical Center).

**Source(s) of monetary or material Support:** Supreme Nudge (CVON2016-04) is funded by the Netherlands Heart Foundation and the Netherlands Organization for Health Research and Development (ZonMw).

## Intervention

## Outcome measures

### Primary outcome

Changes in adherence to the Dutch Dietary Guidelines (i.e, DHD15-index) over 6 or 12 months compared with the control supermarkets.

## **Secondary outcome**

Cardiometabolic outcomes (i.e., HbA1c, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, total cholesterol, total cholesterol/HDL-ratio, triglycerides and waist circumference), along with walking behaviours (i.e., step count) to evaluate effects of the mobile PA app, and intermediate behavioural factors including changes in food purchasing in the supermarket, food decision styles, social cognitive factors in relation to nudges and walking behaviours, customer satisfaction over 6 or 12 months, and acceptance of nudges and technology at 6 or 12 months, all compared with the control arm. In addition the reflexive monitoring will result in a strategic roadmap identifying systemic barriers and facilitators, as well as strategies to overcome identified barriers for future supermarket-based health interventions.

## **Study description**

### **Background summary**

In the Supreme Nudge project, we will study the effects of pricing and nudging strategies in the supermarket – one of the most important point-of-choice settings for food choices – and of a context-specific mobile physical activity promotion app.

The Supreme Nudge trial includes nudging and pricing strategies cluster-randomised on the supermarket level, with: i) control group receiving no intervention; ii) intervention group receiving healthy food nudges (e.g., product placement or promotion) and pricing strategies (taxing of unhealthy foods and subsidizing healthy foods). In collaboration with a Dutch supermarket chain we selected eight stores located in low SEP neighbourhoods.

Across the clusters, a personalized mobile coaching app targeting moderate physical activity (walking behaviour) will be individually-randomised, with: i) control group receiving no intervention; ii) a group receiving the mobile PA app intervention.

The primary outcome is the mean individual change in adherence to the Dutch Dietary Guidelines. Secondary outcomes include cardiometabolic outcomes, and the number of steps per day, healthy food purchasing in the supermarket, food decision styles, social cognitive factors in relation to nudges and in relation to walking behaviours, supermarket customer satisfaction, at 3, and 6 (and 12; depending on participant enrolment date) months and technology acceptance and acceptance of nudges at 6 and 12 months.

The trial is reflexively monitored to support current and future implementation. The findings can guide future research and public health policies on reducing lifestyle related health inequalities and contribute to a supermarket-based health interventions implementation

roadmap.

## **Study objective**

Changing the context in which individuals make lifestyle choices has a sustained impact on the dietary intake and cardiometabolic health.

## **Study design**

The intervention phase will be 6 or 12 consecutive months (depending on participant enrolment date) to account for seasonal variation in shopping and physical activity behaviour and allow measurement of long-term effects. The short-term (3 months) measurements will be used to measure changes in behaviours and intermediate psychological constructs, whereas the longer term follow up (6 and 12 months) will be used to evaluate changes in dietary intake, and for the process-evaluation.

## **Intervention**

This cluster-randomised controlled trial will implement nudging and pricing strategies on the supermarket level, using two trial arms:

- control group receiving no intervention;
- intervention group receiving healthy food nudges and pricing strategies.

An mHealth PA coaching app will be implemented and randomised at the individual level across all supermarket level clusters to prevent clustering of mHealth participants within store locations:

- control group receiving a step count app for tracking of step count data;
- an intervention group receiving the step count app plus the PA coaching app.

## **Contacts**

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## Eligibility criteria

### Inclusion criteria

Potential participants have to meet all of the following criteria in order to be eligible for study inclusion:

- Living in the low SEP neighbourhood surrounding the selected store;
- Aged 30-80 years;
- Self-report to do (or report their partner does) more than half of the household grocery shopping at the selected supermarket and are planning on continuing visiting for the next year;
- Provide written informed consent.

In order to be eligible for additional inclusion in the PA coaching app intervention, a participant must indicate to own a smartphone and use it for text messaging on a regular basis.

### Exclusion criteria

Potential participants who are not able to adequately communicate in the Dutch language will be excluded from the study. Those who are unable to climb a flight of stairs or have a contra-indication to engage in light PA will be excluded from the mobile PA app intervention.

## Study design

## Design

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

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 01-02-2021          |
| Enrollment:               | 360                 |
| Type:                     | Actual              |

## IPD sharing statement

**Plan to share IPD:** Yes

### Plan description

Coded participant-level trial data will be made available on reasonable request when not in violation with participant consent and after approval by the SUPREME NUDGE executive board.

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 30-05-2018       |
| 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  | NL7064                      |
| NTR-old  | NTR7302                     |
| Other    | Hartstichting : CVON2016-04 |

## Study results

### Summary results

Stuber JM, Mackenbach JD, de Boer FE et al. (2020) Reducing cardiometabolic risk in adults with a low socioeconomic position: protocol of the Supreme Nudge parallel cluster-randomised controlled supermarket trial. *Nutr J* 19, 46.

Lakerveld J, Mackenbach JD, de Boer F et al. (2018) Improving cardiometabolic health through nudging dietary behaviours and physical activity in low SES adults: design of the Supreme Nudge project. *Bmc Public Health* 18.