# When the going gets tough: Coping plans as a tool for maintaining loss of overweight

Published: 15-04-2008
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Objective: Aim of the present study is to test the effectiveness of a preventive intervention that helps to maintain healthy diet during difficult situations by means of coping plans (plans how to deal with situations that might threaten adherence...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON31781

**Source**
ToetsingOnline

**Brief title**
Coping plans

### Condition

- Other condition

**Synonym**
obesity, overweight

**Health condition**

overgewicht

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Utrecht
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** coping plans, healthy diet, maintenance, overweight

## Outcome measures

### Primary outcome

Outcome measures: 1) adherence to healthy diet (electronic diet diary qualified by a biomarker) and weight loss, 2) coping plans, coping self-efficacy, and awareness of threats to adherence.

### Secondary outcome

not applicable

# Study description

### Background summary

Research questions: 1) Examine the effectiveness of the intervention in terms of adherence to healthy diet and weight loss (primary outcomes); 2) Examine the effectiveness of the intervention in terms of coping plans, better coping self-efficacy, and awareness of potential threats for maintaining healthy diet (secondary outcomes); 3) Examine to what extent the effectiveness of the intervention is moderated by variables relating to self-regulatory competence. Intervention: A minimal intervention aimed at improving self-management of health behavior that has proven effective in previous research will be tailored to address the topic of maintaining attempts to reduce overweight. Power analysis: With a power of .90 and alpha set at .05, a minimum of 90 patients per condition allows for the detection of medium effects on the primary outcome variable. Time schedule: Year 1: Development and pilot of intervention, recruitment of patients; Year 2: Start of intervention, baseline data-collection; Year 3: Continued intervention and follow-up data-collection; Year 4: data-analyses, preparation of manuscripts.

### Study objective

Objective: Aim of the present study is to test the effectiveness of a preventive intervention that helps to maintain healthy diet during difficult situations by means of coping plans (plans how to deal with situations that might threaten adherence to healthy diet) in overweight people who are at risk for diabetes and motivated to reduce weight.

### Study design

Study design: A prospective randomized controlled design with a 12-month follow-up will be employed.

### Study burden and risks

not applicable

## Contacts

**Public**
Universiteit Utrecht

Postbus 80140
3508 TC Utrecht
NL
**Scientific**
Universiteit Utrecht

Postbus 80140
3508 TC Utrecht
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

Elderly (65 years and older)

### Inclusion criteria

BMI>28 (moderate overweight and obese); motivation for weight loss

### Exclusion criteria

BMI>40 (morbid obese); insuffient mastery of Dutch in speech and writing; currently involved in treatment for overweight.

## Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Prevention

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-03-2008 |
| Enrollment: | 200 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 15-04-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL20539.041.07 |