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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23770

Source
Nationaal Trial Register

Health condition

overweight, obesity, diet, self-regulation intervention, proactive coping

Sponsors and support

Primary sponsor: ZonMW, the Netherlands Organization for Health Research and Development (No. 120610009).
Source(s) of monetary or material Support: ZonMW, the Netherlands Organization for Health Research and Development (No. 120610009).

Intervention

Outcome measures

Primary outcome

Weight (prevention of weight gain) in both short-term (8 weeks) and long-term (at 1 year follow-up), dietary adherence, medical measures (cholesterol, glucose).

Weight and medical measures are obtained through objective means (scale, blood levels). The behavioral and psychological measures will be assessed via questionnaires.

Secondary outcome

Motivation, self-efficacy and proactive coping skills (assessed via questionnaires).

Study description

Background summary

This randomized controlled trial aims to test the effectiveness of a behavioral intervention program targeting proactive coping skills in overweight and obese people (BMI > 25). The experimental program comprises one individual session, 3 biweekly group sessions over a period of 8 weeks, and 2 additional booster sessions 2 and 4 months later. Using a practical 5-step plan, participants are taught to set concrete goals, recognize conditions and barriers to goal achievement, identify potential difficult situations, formulate necessary actions, and consider how to evaluate their progress. The control group receives treatment-as-usual, i.e., education about healthy dietary patterns during two face-to-face sessions.

Primary outcome measures are weight, dietary adherence, and medical measures (Hba1c, blood glucose levels). Secondary measures include motivation, self-efficacy, and proactive coping skills.

Study objective

1. Participants in the experimental condition have more favourable outcomes on the long-term (1 year follow-up) than participants in the control condition. Outcome measures are physiological (e.g., weight), behavioral (e.g., dietary behavior), and psychological (e.g., self-efficacy);

2. Participants who attend additional booster sessions 2 and 4 months after the regular course will have more favourable outcomes than participants who do not attend such sessions.

Study design

1. Baseline;

2. 2 months (after basic sessions);

3. 7 months (after booster sessions);

4. Long-term follow-up (1 year).

Intervention

This randomized controlled trial has the duration of in total 1 year (i.e., it takes 1 year from first to last measurement).

The experimentel intervention consists of one individual session and 3 group sessions (regular course) over a period of 8 weeks. Using a practical 5-step plan previously shown to be effective in improving eating patterns, participants are taught to set concrete goals, recognize conditions and barriers to goal achievement, identify potential difficult situations, formulate necessary actions, and consider how to evaluate their progress.

Two and four months after the regular course, two booster sessions are delivered to the experimental group. These booster sessions are designed to teach participants (coping) planning, a beneficial self-regulatory strategy for the long-term maintenance of weight loss.

The control group receives treatment as usual (information about healthy diet during two face-to-face sessions). Further, we employ an active attention control paradigm by contacting them at exactly the same time-points as the experimental groups participate in sessions. For instance, instead of attending booster sessions , they receive written exercises regarding healthy eating patterns 2 and 4 months after the last session on health education.

Questionnaires will be administered at baseline, after the regular course, after the booster sessions, and at follow-up 6 months after the last booster session. Medical outcomes will be assessed at baseline and at 1-year follow-up.

Contacts

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Eligibility criteria

Inclusion criteria

BMI > 25.

Exclusion criteria

1. BMI < 25;

2. Type II diabetes;

3. Participation in other weight loss programs.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	250

Type:	Actual

Ethics review

Positive opinion Date:	22-02-2011
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	NL2663
NTR-old	NTR2791
Other	ZonMw : 120610009
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A