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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23770

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: ZonMW, the Netherlands Organization for Health Research and Development (No. 120610009).
Overige ondersteuning: ZonMW, the Netherlands Organization for Health Research and Development (No. 120610009).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Baseline;

2. 2 months (after basic sessions);

3. 7 months (after booster sessions);

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

BMI > 25.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. BMI < 25;

2. Type II diabetes;

3. Participation in other weight loss programs.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2009
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-02-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2663
NTR-old	NTR2791
Ander register	ZonMw : 120610009
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A