

Preventing weight gain by lifestyle intervention in a general practice population: the Groningen Overweight And Lifestyle-(GOAL)-randomized controlled trial

No registrations found.

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

Summary

ID

NL-OMON24341

Source

NTR

Brief title

GOAL-study

Health condition

overweight, lifestyle, nurse practitioner
overgewicht, leefstijl, praktijkondersteuner

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)

Source(s) of monetary or material Support: The Netherlands Organization for Health Research and Development (ZonMw)

Intervention

Outcome measures

Primary outcome

A structured physical exam by a specially trained research team was accomplished to measure body weight, body length and waist circumference. The SQUASH-questionnaire was used to determine physical activity. The FFQ (food frequency questionnaire) was used to determine food intake.

These measurements were performed at baseline and repeated after 1 and 3 year.

Secondary outcome

Blood samples were collected to analyze on fasting serum lipids and glucose. Blood pressure was measured twice during the physical exam.

The presence of cardiovascular risk factors, medication use and family history of disease and overweight were documented. Information on general characteristics, quality of life (RAND-36), history of slimming and motivation to change lifestyle (apart for losing weight and physical activity) was measured by standardized questionnaires.

These measurements were performed at baseline and repeated after 1 and 3 year.

Study description

Background summary

According to (inter)national guidelines persistent lifestyle changes are necessary for preventing and managing obesity. Studies on lifestyle interventions have shown a decrease in the risk of type 2 diabetes mellitus and hypertension. Positive changes in lifestyle will improve health status even without losing weight. There's no consensus on the most (cost)-effectiveness way for lifestyle-interventions but factors like attention for nutritional and physical activity aspects, continuity and intensity are important.

In this study we, therefore concentrate on preventing weight gain in a large study group with a body mass index 25 to 40 kg/m² with either hypertension and/or dyslipidemia (n=457). This early focus to prevent (progression of) future comorbidities might have larger long-term success than when aimed at weight loss. In the Netherlands, GPs are often responsible the treatment of risk factors like hypertension and dyslipidemia and they also give lifestyle advices. Lack of time and knowledge to achieve behavioral changes and insufficient continuity of care impede this approach by GPs To avoid these barriers specially trained nurse practitioners may give lifestyle advice (using a standardized computerized software program) instead of GPs.

This study primary investigates the effect (after 1 and 3 year follow-up) of lifestyle advice by NPs on bodyweight, waist circumference, physical activity and food intake in comparison to usual care of the GP. Secondary this effect is investigated on blood parameters like fasting glucose and cholesterol, blood pressure and quality of life.

Study objective

We expect that lifestyle counseling by nurse practitioners will be more effective (also on the long term) on body weight and changes in lifestyle than usual care by the general practitioner.

Study design

At baseline, 1 year follow-up and 3 year follow-up.

Intervention

The intervention group will visit the nurse practitioner for lifestyle counseling according to a standardized computerized software program. During the first year the lifestyle intervention consists of 4 individual visits and 1 feedback moment by phone.

The second and the third year consists of 2 feedback moments by phone and 1 individual visit each year.

The participants in de control group received usual care according to national guidelines from their own GP.

Contacts

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Eligibility criteria

Inclusion criteria

1. Between 40 and 70 years
2. BMI between 25-40 kg/m²
3. Hypertension or dyslipidemia.

Exclusion criteria

1. Diabetes Mellitus
2. Hypothyroidism
3. Pregnancy
4. Liver- or kidneydisease
5. Current treatment for malignancy
6. Shortened life expectancy
7. Mentally illness
8. Addiction to alcohol and drugs.

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):	01-04-2005
Enrollment:	600
Type:	Actual

Ethics review

Positive opinion	
Date:	02-07-2008
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	NL1316
NTR-old	NTR1365
Other	ZonMw : 62000016
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A