

Multidisciplinary treatment program for overweight in a primary care setting

Submission date

28/04/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

28/04/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

02/05/2019

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

N/A

Study information

Scientific Title

Multidisciplinary treatment program for overweight in a primary care setting

Study objectives

Treatment of overweight by a dietician has a larger effect on weight loss and risk profile as compared to no treatment. Additional treatment by a physiotherapist is beneficial for long-term maintenance of the result achieved as compared to treatment by a dietician only.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Overweight

Interventions

1. Monthly meetings with a dietician during a half year period
2. Monthly meetings with both a dietician and a physiotherapist during a half year period
3. Routine health care (control)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Change in weight.

Secondary outcome measures

Effect evaluation:

1. Change in BMI and waist circumference
2. Change in blood pressure, blood glucose, blood lipids and Framingham risk score
3. Change in energy intake and energy consumption
4. Change in physical condition
5. Change in use of health care and medication use

Process evaluation:

6. Response
7. Compliance
8. Program-associated costs and workload

Overall study start date

09/03/2006

Completion date

30/06/2007

Eligibility**Key inclusion criteria**

1. ≥ 18 and < 65 years of age
2. Body mass index (BMI) ≥ 28 and $< 35 \text{ kg/m}^2$
3. Knowledge of the Dutch language
4. Participate in the Utrecht Health Project, a community-based prospective cohort study in Leidsche Rijn, part of the city of Utrecht, The Netherlands

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150

Total final enrolment

134

Key exclusion criteria

1. Participate in any other former or current intervention related to overweight
2. Already under treatment by a dietician or physiotherapist
3. Known diagnosis of depression, schizophrenia, anxiety disorder, binge eating disorder or bulimia nervosa
4. Pregnancy
5. Moving plans

Date of first enrolment

09/03/2006

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht (UMCU)

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details

P.O. Box 85500

Utrecht

Netherlands

3508 GA

Sponsor type

University/education

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

Government

Funder Name

Dutch Ministry of Health, Welfare and Sport

Alternative Name(s)

Dutch Ministry of Health, Welfare and Sport, VWS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010	02/05/2019	Yes	No