

Effect of a Body Area Network (BAN) as an additional factor in a weight reduction program by patients with obesity: BANdeBuik

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/07/2009	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR353; MEC: P03-27

Study information

Scientific Title

Acronym

BANdeBuik

Study objectives

The use of a Body Area Network (BAN) in a weight reduction program has a positive effect, due to a higher compliance, on weight loss, total body fat and body fat distribution.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group 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

Obesity, Sleep apnoea

Interventions

Intervention group: a weight reduction program, that consists of a training schedule and a diet, and feedback on the compliance of the training schedule measured by a Body Area Network (BAN).

Control group: a weight reduction program, that consists of a training schedule and a diet.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Weight loss, measured by body weight every month.

Secondary outcome measures

1. Fat free mass, measured by an bio-electrical impedance analysis
2. Total body fat, measured by an bio-electrical impedance analysis
3. Body fat distribution, measured by the waist-to-hip ratio
4. Utility of the BAN, measured by an semi-structured in-depth interview

Overall study start date

30/03/2003

Completion date

08/09/2005

Eligibility**Key inclusion criteria**

1. Body Mass Index between 30 - 40 kg/m²
2. A ratio of waist circumference to hip circumference greater than 1.0
3. Age range between 18 and 60 years old
4. A normal glucose tolerance and plasma lipid profile
5. A stable weight (\pm 2kg) for 6 months before study entry
6. A minimum of 6 months without any weight reduction programs

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

20

Key exclusion criteria

Patients will be excluded if:

1. They smoke
2. They consume more than two alcoholic drinks per day
3. They suffer from claudicate intermittent or angina pectoris
4. They have osteoarthritis of the lower extremity
5. They have active cancer, type 1 diabetes or type 2 diabetes
6. They have undergone any surgery to lose weight

7. Dietary fat reduction or exercise was contraindicated for medical reasons
8. They use medications known to affect weight gain or loss
9. They have a diagnosis of bulimia

Date of first enrolment

30/03/2003

Date of final enrolment

08/09/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Medisch Spectrum Twente

Enschede

Netherlands

7500 KA

Sponsor information

Organisation

Medisch Spectrum Twente (Netherlands)

Sponsor details

P.O. Box 50000

Enschede

Netherlands

7500 KA

Sponsor type

Hospital/treatment centre

Website

<http://www.mstwentenl/>

ROR

<https://ror.org/033xvax87>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Medisch Spectrum Twente (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