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

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/07/2009	Nutritional, Metabolic, Endocrine	[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Weight loss, measured by body weight every month.

Key secondary outcome(s))
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

Completion date
08/09/2005

Eligibility

Key inclusion criteria
1. Body Mass Index between 30 - 40 kg/m^2
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 (± 2kg) for 6 months before study entry
6. A minimum of 6 months without any weight reduction programs

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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)

ROR
https://ror.org/033xvax87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Medisch Spectrum Twente (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration