SURPLUS-trial

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23994

Source
Nationaal Trial Register

Brief title
SURPLUS

Health condition

Bariatric surgery

Sponsors and support

Primary sponsor: Investigator Initiated Study / Obesity Center Catharina Hospital Eindhoven
Source(s) of monetary or material Support: Covidien material funding (remote devices)

Intervention

Outcome measures

Primary outcome

Numeric Rating Scale for decision making after 12 months

Secondary outcome

Verbal Descriptor Scale satisfactorily patients and caretakers Quality of life with RAND 36 questionnaire Reduction in weight and comorbidities Number of additional telephone

contacts not leading to medical intervention Frequency technical failures of the wireless monitoring devices

Study description

Background summary

Telehealth has a great additinal value to standard care. The use in bariatric patients is described rarely, even though this group seems to be particularly suitable. These patients have to attend a postoperative follow-up program for 5 years, are often young adults and are internet minded nd could benefit from motivational coaching. Now, online coaching modules and remote monitoring devices are available. The real surplus value of these additions is still uncertain. In a randomised controlled the surplus value will be investigated.

Study objective

Online coaching modules and wireless biometric measurements have surplus value in addition to standard coaching program after bariatric surgery

Study design

Baseline, 3 and 12 months

Intervention

150 selected patients postoperatively in the obesity center randomly divided into 3 groups; (1) standard counseling (2) standard counseling + online coaching modules (3) standard counseling + online coaching modules + wireless remote monitoring for the period of 12 months

Contacts

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Eligibility criteria

Inclusion criteria

- A body mass index above 40 kg/m2 or above 35 kg/m2 with related comorbidity (hypertension, diabetes type 2, hyperlipidaemia, obstructive sleep apnoea syndrome or joint arthritis of lower limbs)

- A gastric sleeve / bypass / revision planned

- Completed the bariatric screening questionnaire online

- Having ongoing access to internet

- Ability to use a model of mobile device (smartphone or tablet) with any version of the Android or iOS platform

- Age of 18 years or more

- Ability to read and write the Dutch language

- Signed informed consent

Exclusion criteria

Not fulfilling the selectioncriteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40935
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4647
NTR-old	NTR4790
CCMO	NL50324.060.14
OMON	NL-OMON40935

Study results