SURPLUS-trial ;A randomized trial to assess the SURPLUS value of telehealth for the Catharina Obesity Centre

Published: 30-10-2014
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Determining the surplus value of telehealth in addition to the standard program after a bariatric procedure

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON40935

Source
ToetsingOnline

Brief title
SURPLUS-trial

Condition

- Gastrointestinal therapeutic procedures

Synonym
bariatric procedure / obesity

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Covidien,Industrie Covidien financiert de wireless devices

Intervention

Keyword: bariatric surgery, ehealth, telehealth, telemonitoring

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 surplusvalue of these additions is still uncertain

Study objective

Determining the surplus value of telehealth in addition to the standard program after a bariatric procedure

Study design

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

Study burden and risks

The sub-group randomized to the use of wireless monitoring devices will have to read and hear about its use. Patients are encouraged to use the online coaching modules and wireless devices, however it is not obligated. The extent of the burden is assumed to be small. Furthermore there seems no specific risk associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Completed the questionnaire online
- Having ongoing access to internet
- Ability to use a model of mobile device (smartphone or tablet) form the list
- 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
- Age of 18 years or more
- Ability to read and write the Dutch language
- Signed informed consent

Exclusion criteria

Not fulfilling the selection criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Not approved

Date:	30-10-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23994
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50324.060.14
OMON	NL-OMON23994