Telemonitoring of obese patients with a digital electronic weight scale

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36777

Source
ToetsingOnline

Brief title
TOP trial

Condition

- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
gastric bypass patients, morbid obesity, serious overweight

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: Inotive Solutions B.V. ,onderzoeksgeld afdeling Heelkunde Rode Kruis Ziekenhuis

Intervention

Keyword: gastric bypass, obesity, telemonitoring, weight

Outcome measures

Primary outcome

Percentage of 'measured weeks' during the first postoperative year, calculated as a minumum of 1 available measurement per week/52 weeks. Feasibility of telemonitoring, i.e., success, will be defined as weight measurements for 80% of 52 postoperative weeks (42 *week* measurements).

Secondary outcome

-Percentage of measured days in the first postoperative year, calculated as number of weigh days divided by 365 days

-Percentages of weight loss and excess weight loss from moment of inclusion to surgery

-Percentages of weight loss and excess weight loss from surgery to 1 year postoperatively

-Patient satisfaction based on responses to satisfaction questions

-Health worker satisfaction based on responses to satisfaction questions

Successful excess weight loss is defined as at least 50% excess weight loss 1 year after surgery

Study description

Background summary

Bariatric surgery is the most effective treatment option for patients with extreme obesity and has become increasingly popular. Successful bariatric

surgery is defined as at least 50% excess weight loss 1 year after surgery. One of the most important factors that contribute to success is postoperative follow-up. Patient weight loss should be monitored closely since weigth regain is the most important long-term threat for these patients.

Study objective

The goal of this study is to investigate the feasibility of distant, internet-based follow-up and monitoring of the weigth of 20 gastric bypass patients. Our research results will determine whether or not the use of the Youw8 weight scale is attainable and desirable in the contact of the preoperative and postoperative follow-up of gastric bypass patients.

Study design

Prospective intervention study

Study burden and risks

After informed consent has been obtained by the researcher, treating physician and/or specialised nurse, the patient will receive the weight scale with user's manual. Patients are requested to install the program and weigh themselves with this system from this moment on, preferably daily, but at least once a week. The period of hospital admission will be excepted from measurements. After dismissal, the weighing frequency of at least once a week is resumed and the patient will be invited to visit the out patient clinic according to the protocolled frequencies of 6 weeks, 3 months, 6 months and 12 months postoperatively. The 12-month visit will be the study end point.

Included patients will be asked to fill in satisfaction-related questions on the following time points:
1) after installation of the program (possible answers: very dissatisfied, somewhat unsatisfied, neutral, somewhat satisfied, very satisfied)
2) after the end of the study 12 months after surgery
a) on satisfaction with regard to the program (mogelijke antwoorden: erg ontevreden, enigszins ontevreden, neutraal, enigszins tevreden, zeer tevreden)
b) whether they would recommend the weight scale to others (possible answers: definitely not, probably not, maybe not, maybe yes, probably yes, surely yes)

The risk associated with participation in this study is considered negligible.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-age 18 years and older
-maximum weight of 150 kg (measured on the weigth scale at the out patient clinic)
-patient is planned for laparoscopic or open gastric bypass surgery (or similar procedure) or gastric sleeve procedure
-consent for surgery by Dutch Obesity Clinic
-consent for surgery by anaesthesiologist
-available internet connection
-sufficient knowledge of the Dutch language in order to comply to weighing instructions

Exclusion criteria

-adolescents and children
-gastric banding surgery
-no available internet connection

-insufficient knowledge of the Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	digital weight scale youw8 body monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-05-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL34902.094.10