

BePATIENT-trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22698

Source

NTR

Brief title

n/a

Health condition

morbid obesity; bariatric surgery; eHealth; telemedicine

morbiditas obesitas; bariatrische chirurgie; eHealth; telegeneeskunde

Sponsors and support

Primary sponsor: Investigator Initiated Study

Source(s) of monetary or material Support: Initiator = sponsor = fund

Intervention

Outcome measures

Primary outcome

The Body Mass Index at 2 years postoperatively

Secondary outcome

1. Quality of Life (RAND36)

2. Evolution related comorbidities (treatment severity)
3. Program commitment (Neubert & Cady 2001)
4. Additional contacts/visits (n)
5. Technical errors biometric devices (n)
6. Length of stay in hospital (days)
7. Return to work (days)
8. Patients' satisfaction (Numeric Rate Scale)
9. Health care suppliers' satisfaction (Numeric Rate Scale)

Study description

Background summary

Long-term effect of bariatric surgery is influenced by the compliance with a follow-up program. This commitment could be improved by eHealth. However, to which extent this benefit is or whether it should be an interactive website or include remote monitoring as well remains unclear. This study compares a conventional follow-up program to programs including an educational portal and remote monitoring to assess the value of eHealth for bariatric surgery.

Study objective

Assessing the value of online education with and without remote monitoring added to standard perioperative bariatric care

Study design

1, 3, 6, 9, 12, 18 and 24 months after bariatric procedure

Intervention

eHealth program by BePATIENT containing

1. Online education module

- eLearning programs
- Videos
- Patient network
- Video consulting

2. Remote monitoring

- Weighing scale
- Blood pressure
- Activity tracker
- Oximeter

200 subjects will be allocated to receive in a 2:1:1 distribution into

1. standard perioperative bariatric care versus
2. added online education versus
3. added online education and remote monitoring

Contacts

Public

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Eligibility criteria

Inclusion criteria

1. Completed the bariatric screening questionnaire online
2. Having ongoing access to internet
3. Ability to use a model of mobile device (smartphone or tablet) with any version of the Android or iOS platform
4. 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, gastroesophageal reflux disease or joint arthritis of lower limbs)
5. A primary bariatric procedure planned (Gastric sleeve / Gastric bypass)
6. Age of 18 years or more
7. Ability to read and write the Dutch language
8. Signed informed consent

Exclusion criteria

Not fulfilling the selection criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control: Active

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-04-2017
Enrollment: 200
Type: Anticipated

Ethics review

Positive opinion
Date: 19-11-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43037
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6641
NTR-old	NTR6827
CCMO	NL56992.100.16
OMON	NL-OMON43037

Study results

Summary results

n/a