Effect of a PReoperative Information Video on Anxiety in Deep Brain Stimulation surgery patients

Published: 22-03-2012
Last updated: 01-05-2024

Our aim is to investigate whether patients who are informed by video will have less preoperative anxiety than the patients who receive usual information.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37791

Source
ToetsingOnline

Brief title
PRIVA-DBS

Condition

- Other condition
- Movement disorders (incl parkinsonism)
- Nervous system, skull and spine therapeutic procedures

Synonym
preoperative anxiety in Parkinson's disease patients

Health condition

pre-operatieve angst

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Deep Brain Stimulation, Parkinson disease, Patient education

Outcome measures

Primary outcome

The main study endpoint is the change scores on the Spielberger State Trait Anxiety Inventory (STAI) between the intervention group and the control group at different time points.

Secondary outcome

- Visual analogue scale (VAS) is a validated instrument for measuring anxiety.

- The Amsterdam Preoperative Anxiety and Information Scale (APAIS) is a six-item questionnaire to assess patients* anxiety level and information requirement in the preoperative phase.

Study description

Background summary

Parkinson*s disease (PD) patients benefit from Deep Brain Stimulation (DBS). DBS is a surgical treatment used to treat the motor symptoms of PD. A large part of the surgery is performed while the patient has local anaesthesia. Altogether the surgery takes about eight hours and is a profound experience for patients, since they are awake during most parts of the surgery.
Preoperative anxiety is common in surgical patients, with an incidence of 60 to 92%. In neurosurgical patients an incidence of preoperative anxiety of 89% is reported. There is no information available on incidence and severity of preoperative anxiety in patients undergoing DBS surgery. Previous studies about

preoperative anxiety have shown that preoperative fears are most commonly related to questions of whether the surgery will be effective, whether there is postoperative pain, and whether there is fear for being awake during surgery. The effect of preoperative multimedia information on anxiety was measured in patients undergoing surgical procedures of the arm or leg under regional anaesthesia, but we consider this to be different as compared to DBS surgery. Currently, DBS surgery patients receive a lot of information before their operation in the AMC. They get information leaflets and several educational interviews. Despite these efforts, we notice that patients still have a lot of questions before surgery and that they are very tense. This is why improvement of the information procedure is needed. We want to investigate the effect of an informative video on preoperative and perioperative anxiety.

Study objective

Our aim is to investigate whether patients who are informed by video will have less preoperative anxiety than the patients who receive usual information.

Study design

The study is an open-label randomized controlled trial. The trial is carried out in the Academical Medical Center Amsterdam (AMC). Patients will be followed over a period of three months.

Intervention

Information video
Patients are randomly allocated to the intervention group (watching the video and standard care) or a control group (standard care).
A video explaining every step of surgery is shown to patients participating in the intervention group. This video includes a description of the stereotactic frame, MRI-scan, surgical procedure, risks involved; including the risks of brain hemorrhage (1-2%) and infection (5%). It also provides information about the postoperative procedures, postoperative setting of stimulation and visits to the outpatient clinic. After this video there is time for patients to ask questions and more explanation of items that are addressed in the video. Patients can take the video home to watch it and show it to their family and/or friends.
The control group receives standard care; standard information by a DBS nurse and neurologist. This also includes a description of the stereotactic frame, MRI-scan, the surgical procedure, risks and (side) effects involved. The participants also get information leaflets to read.

Study burden and risks

For this study, participants have to fill in questionnaires and the

intervention group patients will watch an extra video. We consider that the chance of increasing anxiety due to the study procedures (e.g., video, questionnaires about anxiety) is small. If this trial confirms our hypothesis, patients will be less anxious in the future. Therefore we consider the risks and burden for the patient to be well in proportion to the potential value for the enrolled patients.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Parkinson's disease patients planned for DBS surgery;
The patient is able to communicate adequately in Dutch;
The patient is 18 years or older

Exclusion criteria

Previous functional stereotactic neurosurgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL38657.018.11