

Enhancement of patient's autonomy by active role training with operative patients: Patient Active Role Training

Submission date 15/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/06/2015	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Shared decision making in surgical patients

Acronym

PART-Studie

Study objectives

The hypothesis is that patients with wish of autonomy, who will receive structured information, will have a better outcome measured by earlier fulfilled discharge criteria from the hospital influence on length of stay.

On 04/01/2011 the following changes were made to the trial record:

1. The overall trial end date was changed from 30/05/2008 to 30/05/2010
2. The target number of participants was changed from 100 to 175.

On 09/06/2015 the following changes were made to the trial record:

1. The overall trial start date was changed from 25/04/2008 to 01/10/2007.
2. The overall trial end date was changed from 30/05/2010 to 09/06/2010.
3. The target number of participants was changed from 175 to 280.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Charité - University Medicine Berlin, 18/03/2008

Study design

Prospective randomised controlled single-centre interventional study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Indication for operation in traumatology and general surgery

Interventions

The inclusion of the patients takes place in the anaesthesiology premedication clinic. After the education, a computer assisted questionnaire will be performed. This questionnaire contains a special questionnaire of the preference of autonomy. If the score of the patient is above the median score the patient gets randomised. This so called 'active decision' group gets a booklet. This booklet contains informations of essential processes for the preparations before and after operations.

In the control group the participants do not obtain any additional information.

In both groups, pain, nil per os, mobilisation were recorded.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

1. Analgesia
2. Post-operative nausea and vomiting, using the Visual Analogue Scale (VAS: 0 = no pain/no vomiting, 10 = unbearable pain/extreme vomiting)
3. Post-Anaesthesia Discharge Scoring System (PADSS)

PADSS will be measured daily during the patient's study participation in the Charité hospital (longest time until the 5th day of hospital stay).

Key secondary outcome(s)

1. World Health Organization (WHO)-5 Well Being Index
2. Patient Involvement in Care Scale
3. Sense of coherence
4. Autonomy Preference Index

The patients will be monitored and these parameters will be surveyed every day until they fulfill the hospital discharge criteria (measured by PADSS) up to hospital discharge at fifth of the patient's stay.

Completion date

09/06/2010

Eligibility

Key inclusion criteria

1. Written informed consent
2. German speaking
3. Patients of traumatology and surgery
4. Aged 18 years or older, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients who have no wish for shared decision
2. Accommodation in an institution due to an official or judicial order
3. No written consent from patient
4. Unwillingness to allow storage and sharing of anonymised disease data in the context of the

clinical study

5. Aged less than 18 years

6. Member of staff of the Charité

7. No working knowledge of German

8. Planned sojourn on intensive care unit

Date of first enrolment

21/04/2008

Date of final enrolment

09/06/2010

Locations

Countries of recruitment

Germany

Study participating centre

Charite - Universitätsmedizin Berlin

Berlin

Germany

D-13353

Sponsor information

Organisation

Charite - University Medicine Berlin (Charite - Universitätsmedizin Berlin) (Germany)

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Charite - University Medicine Berlin (Charite - Universitätsmedizin Berlin) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration