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

Submission date	Recruitment status	[ ] Prospectively registered
15/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/06/2015	Surgery	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 measure
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).

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

Overall study start date
01/10/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
280

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 - Universitatsmedizin Berlin
Berlin
Germany
D-13353

Sponsor information

Organisation
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

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Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration