

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

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

**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 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.

### **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 - Universitätsmedizin Berlin

Berlin

Germany

D-13353

# Sponsor information

## Organisation

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

## Sponsor details

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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 - Universitätsmedizin 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