

# Step by Step steady on your feet - a training program to regain mobility and independence after hip or pelvic fracture

<b>Submission date</b> 21/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/06/2011	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 19/04/2017	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<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

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## **Additional identifiers**

**Protocol serial number**  
01EC1007A

## **Study information**

### **Scientific Title**

Multifactorial intervention to reduce fear of falling after a hip or pelvic fracture: a prospective, randomised controlled trial - subproject No. 5 of the consortium Prevention and Rehabilitation of Osteoporotic Fractures in Disadvantaged Populations

### **Acronym**

PROFinD 5

### **Study objectives**

Main hypothesis: Rehabilitation + fear of falling - intervention are more effective than standard inpatient rehabilitation in regard to physical activity and falls efficacy three months after discharge.

Minor hypothesis: To determine the effect of the intervention on fear of falling, perceived control over falling, depression, general anxiety, quality of life and functional recovery three months after discharge.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The ethics committee of the University of Tuebingen, 04/04/2011, ref: 113/2011BO2

### **Study design**

Prospective randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Hip or pelvic fracture

### **Interventions**

## Intervention group

Multifactorial intervention to increase physical activity and reduce fear of falling. It comprises of 8 additional personal contacts during the inpatient rehabilitation period, 4 telephone contacts and one home visit during two months after discharge.

The intervention consists of six modules:

1. Training of a relaxation technique
2. Objectives in mobility and plan to reach them
3. Fall-related cognitions and emotions, managing critical situations
4. Individual exercise programme
5. Realising exercises and activities regularly at home
6. Fall hazards

Intervention and control group:

All participants receive standard inpatient rehabilitation.

Interventions and assessments are delivered by different teams; the assessment team is blinded to the different groups by the study centre. Because communicating of their status by the participants a complete blinding is probably not possible.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome(s)

1. Physical activity
  - 1.1. Sensor based activity monitoring
  - 1.2. Phone-FITT physical activity questionnaire
2. Falls Efficacy
  - 2.1. Short Falls Efficacy Scale international [Short FES-I]
  - 2.2. Perceived ability to manage risk of falls or actual falls

Measured at: T0: in the first week after admission to inpatient rehabilitation, T1: between two weeks after T0 and discharge, T2: 4 months after T0

## Key secondary outcome(s)

1. Fall-related Criteria - Percived Control Over Falling [PCOF]
2. Mental Health Criteria
  - 2.1. Hospital Anxiety & Depression Scale [HADS]
  - 2.2. Revised Anxiety Control Questionnaire subscale emotion and stress [ACQ-R]
  - 2.3. Revised Acceptance and Action Questionnaire II [AAQ-II]
3. Body Functions
  - 3.1. Short Physical Performance Battery [SPPB]
  - 3.2. Rivermead Mobility Index
4. Quality of life
  - 4.1. EURO QoL-5
  - 4.2. WHO-QoL Old, subscale social participation

Measured at: T0: in the first week after admission to inpatient rehabilitation, T1: between two weeks after T0 and discharge, T2: 4 months after T0

**Completion date**

31/08/2013

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 20/02/2012:

1. Hip or pelvic fracture as main diagnosis for admission to inpatient rehabilitation
2. Age: 60 years and older
3. Concern about falling (Fear of Falling screening instrument)

Previous inclusion criteria:

1. Hip or pelvic fracture within the last 8 weeks
2. Age: 60 years and older
3. Concern about falling (Fear of Falling screening instrument)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Delirium
2. Shortsightedness (> 20/400)
3. Mental disease like suicidality, acute psychosis, schizophrenia, bipolar disorder, schizo-affective disorder
4. Cognitive impairment Short Orientation-Memory-Concentration (SOMC)  $\geq 10$
5. Living in a nursing home when the fall occurred
6. Not able to understand and speak German language
7. No telephone extension or not able to communicate over the telephone
8. Moderate or severe aphasia (amnesic aphasia is no exclusion criteria), apraxia of speech
9. Capacity too low to endure the assessment
10. Diseases, that require additional time-consuming therapy during rehabilitation period (like dialysis)
11. Other medical exclusion criterias like severe inflammations or infections, mechanical instability of the osteosynthesis, terminal status
12. Place of domicile not reachable with the public transport of the region of Stuttgart

**Date of first enrolment**

26/04/2011

**Date of final enrolment**

31/08/2013

# Locations

## Countries of recruitment

Germany

## Study participating centre

Robert-Bosch-Krankenhaus

Stuttgart

Germany

70376

# Sponsor information

## Organisation

Robert Bosch Hospital (Robert-Bosch-Krankenhaus) (Germany)

## ROR

<https://ror.org/034nkkr84>

# Funder(s)

## Funder type

Government

## Funder Name

Federal Ministry of Education and Research (BMBF) (Germany) (ref:01EC1007A)

## Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Germany

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	01/05/2017		Yes	No