

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

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

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

26/04/2011

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

Age group

Adult

Sex

Both

Target number of participants

102 participants

Key exclusion criteria

1. Delirium
2. Shortsightedness (> 20/400)

3. Mental disease like suicidality, acute psychosis, schizophrenia, bipolar disorder, schizoaffective disorder
4. Cognitive impairment Short Orientation-Memory-Concentration (SOMC) ≥ 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)

Sponsor details

c/o Dr. Clemens Becker

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Sponsor type

Hospital/treatment centre

Website

<http://www.rbk.de/>

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 Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2017		Yes	No