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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

Registration date
06/06/2011

Overall study status
Completed

Last Edited
19/04/2017

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Scientific

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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 regulary 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) ≥ 10
5. Living in a nursing home when the fall occured
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
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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?
Protocol article	protocol	01/05/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes