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Prevention and rehabilitation of osteoporotic fractures In disadvantaged populations 2 – subproject 3: a training program to regain mobility and independence after hip or pelvic fracture

Submission date
22/07/2015

Recruitment status
No longer recruiting

Registration date
28/07/2015

Overall study status
Completed

Last Edited
02/05/2019

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
Background and study aims
Hip and pelvic fractures are among the most serious fall-related injuries and is the leading cause of hospitalization among people aged over 65 years. Following surgery, most people are not able to function as well as they did and are not able to be so physically active. Also, there is a very high risk of death among this population group after hip surgery, with 5-10% of patients dying within 30 days of surgery. One year after surgery, this number increases to 33%. It has been shown that functional performance can be improved after hip or pelvic fractures, but there are no specific recommendations for the treatment following inpatient rehabilitation yet. For example, cognitive (thinking) functions play a crucial role in the rehabilitation of functional performance. Lower cognitive capabilities are associated with longer functional recovery times after surgery, an increased risk of falling and more severe fall-related impairments (or disabilities). Since current outpatient care is scarce, there is a need of specific treatments for cognitively impaired persons with hip or pelvic fractures in the period after inpatient rehabilitation. Therefore, the aim of this study is to examine the effects of a 4-month multifactorial treatment following inpatient rehabilitation. The aim is to improve the care for hip and pelvic fracture patients with a just developing to moderate cognitive impairment and their caregivers in the transition from inpatient rehabilitation to the homely environment.

Who can participate?
Older persons (≥ 65 years) with fall-related hip or pelvic fractures and just developing to moderate cognitive impairments

What does the study involve?
Two groups are compared. One group (control group) receives the standard rehabilitation and the standard non-controlled care after discharge (e.g., physiotherapy, if prescribed by a doctor). During rehabilitation, participants are given information about treatments after hip or pelvic

fractures including a standardized exercise program. The other group (treatment group) additionally receive a 4-month multifactorial treatment to increase physical activity and improve functional performance. The treatment includes an exercise program, carried out two times per week supervised by a volunteer instructor, an unsupervised home training, promotion of physical activity, care counseling for the patient and problem solving for the informal caregivers. Physical activity, functional performance and other variables such as fear of falling, falls, and quality of life are measured before the beginning of the program, after the program and three months later. Also, the situation of informal caregivers (e.g., depressive symptoms, physical complaints) and the costs of the program are recorded.

What are the possible benefits and risks of participating?
Risks of participating in this study are considered to be low, since it is a non-invasive and drug-free study. Exercises during the exercise program may lead to sore muscles, which can cause pain and reduced joint mobility. Although the performed exercises (i.e., strength, balance, walking, and activities of daily living) may lead to a slightly increased risk of falling during training, we expect a substantial improvement of functional performance after the training (i.e., improved strength, balance and walking ability). These improvements will reduce the risk of falls and increase independence (i.e., perform important activities of daily living) in patients suffering from hip or pelvic fractures. Participants get individual training schedules and safety instructions by experts (physiotherapists/sports scientists) to keep the risks during training as low as possible. All participants will be insured. The control group receives information about treatments after hip/pelvic fractures including a standardized exercise program. Regarding the situation of caregivers, an improved mental health following treatment might reduce their burden of providing support. Results of this study can contribute to an improved care after discharge from rehabilitation in cognitive impaired persons with a hip/pelvic fracture. Given the possible performance improvements and low risks, we assume that the benefits outweigh the risks. The program can be easily implemented into clinical practice.

Where is the study run from?
There are six centers taking part in this study:
Robert Bosch Hospital, Clinic for Geriatric Rehabilitation (Stuttgart, Germany), Agaplesion Bethanien Hospital gGmbH, Geriatric Center at the University of Heidelberg (Heidelberg, Germany) , Mannheim University of Applied Science, Department of Social Work (Mannheim, Germany), University Medical Center Mainz, Interdisciplinary Centre for Clinical Trials (IZKS), Ulm University, Institute of Epidemiology and Medical Biometry, University Medical Center Hamburg-Eppendorf (UKE), Department of Medical Sociology and Health Economics. Robert Bosch Hospital is the lead center.

When is the study starting and how long is it expected to run for?
February 2015 to January 2019

Who is funding the study?
Federal Ministry of Education and Research of the Federal Republic of Germany (Berlin, Germany)

Who is the main contact?
Dr Klaus Pfeiffer
klaus.pfeiffer@rbk.de

Study website
http://www.profind.info/

Contact information

Type(s)
Scientific

Contact name
Dr Klaus Pfeiffer

ORCID ID
http://orcid.org/0000-0001-6486-4287

Contact details
Auerbachstr. 110
Stuttgart
Germany
70376

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01EC1404A

Study information

Scientific Title
Prevention and rehabilitation of osteoporotic fractures In disadvantaged populations 2 – subproject 3: a multifactorial intervention for osteoporotic fracture patients with incipient to moderate cognitive impairment and their caregivers: a dual-center randomized controlled trial

Acronym
PROFinD 2 / OFCare

Study hypothesis
Primary hypothesis:
1. Rehabilitation and a following multifactorial intervention in the patient’s home are more effective than standard rehabilitation in regard to physical activity and functional performance four/seven months (post-intervention / follow-up) after rehabilitation.

Secondary hypotheses:
1. Rehabilitation and a following multifactorial intervention in the patient’s home are more effective than standard inpatient rehabilitation in regard to fear of falling, falls efficacy, falls, activities of daily living, quality of life, depressive symptoms, and behavioral problems of the patient four / seven months (post-intervention / follow-up) months after rehabilitation.
2. Rehabilitation and a following multifactorial intervention in the patient’s home are more

effective than standard inpatient rehabilitation in regard to caregiver´s (if existing) depressive symptoms, sense of competence, negative problem orientation, physical complaints, and leisure time activities four / seven months (post-intervention / follow-up) months after rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics committee of the University of Tuebingen, Germany, 08/06/2015, ref: 150/2015BO1
2. Ethics committee of the Medical Faculty Heidelberg, University of Heidelberg, Germany, 18/06 /2015, ref: S-256/2015

Study design
Interventional prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Condition
Patients with hip or pelvic fractures and an incipient to moderate cognitive impairment

Interventions
Control group:
1. Standard inpatient rehabilitation with appropriate training
2. Additional information about motor training and activity after hip or pelvic fractures (one contact during rehabilitation) including a brochure containing a standardized exercise program after hip or pelvic fractures as a homework
3. Usual non-controlled care including physiotherapy, if prescribed by attending physician after rehabilitation

Intervention group:
1. Standard inpatient rehabilitation with appropriate training
2. Additional information about motor training and activity after hip or pelvic fractures (one contact during rehabilitation) including a brochure containing a standardized exercise program after hip or pelvic fractures as a homework
3. Information about the program
4. Usual non-controlled care including physiotherapy, if prescribed by attending physician after rehabilitation

5. Additional multifactorial intervention to increase physical activity and improve functional performance. The intervention consists of the interventions mentioned above and the following two modules:

Module 1: Training intervention [duration: 4 months; delivered by exercise instructor (EI) & volunteer instructor (VI)] over 4 months after rehabilitation:
1. Information about the intervention after randomization; training starts at patient's home after the assessment T1b
2. Assessment of mobility and independency, definition of mobility and participation goals, introduction of the VI, provision and introduction of an individual training program, clarifying / discussion of security aspects during training, reduction of fall risk in daily life, information on what to do after a fall
3. Exercise program, 2 times per week for approx. 30 minutes (+ practice of a defined activity of daily living), supervised by VI (VI supervised by EI), maximum duration of a visit is 2 hours
4. Unsupervised home training, 1 - 4 times per week for approx. 10-20 minutes, depending on the capacity of the patient and caregiver support
5. Initial home visit (maximum duration: 2 hours) and 2 additional home visits (EI + VI)
6. 5 telephone calls (EI)

Module 2: Care counseling with a focus on promotion of activity and participation (duration: 3.5 months)
1. Implemented by social worker
2. Starts after the first home visit by the EI

Hip / pelvic fracture patient:
1. Clarifying of care situation (modified Care Counselling Inventory; Hendlmeier et al. 2014)
2. Promotion of participation

Informal caregiver (if existing):
1. Assessment of caregiver resources and burden (card sorting procedure), problem solving intervention for 3.5 months after the initial home visit (D'Zurilla, T. J., & Nezu, A. 2006; Pfeiffer et al. 2014)
2. Caregiver's role in the implementation of mobility and participation goals of the patient
3. 12 information letters on caregiving issues

Module 2 contains one home visit (maximum duration: 2.5 hours) and 5 telephone calls. Two additional home visits and four additional phone calls with the patient / caregiver are possible in cases of urgency or complex situations.

Intervention Type
Mixed

Primary outcome measure
1. Physical activity: Sensor based activity monitoring (activPAL™, 72 hours). Measured at: T1b (at home, after rehabilitation), T2 (after the 4-month program), T3 (follow-up; three months after completion of the program)
2. Physical Performance: Short Physical Performance Battery (SPPB; DynaPort). Measured at: T1a (at the end of rehabilitation), T1b (at home, after rehabilitation), T2 (after the 4-month program), T3 (follow-up; three months after completion of the program)

Secondary outcome measures

1. Patient-related measures
Falls self-efficacy / Fear of falling: Short Falls Efficacy Scale international (Short FES-I), Fear of Falling Questionnaire Revised (FFQ-R):
1.1. **Falls: Falls diary / weekly telephone call
1.2. Depressive symptoms: Montgomery-Asberg Depression Scale (MADRS)
1.3. Activities of daily life: *Barthel-Index, and **study specific questions
1.4. Health related quality of life: **Quality of Life in Alzheimer's Disease (Qol-AD)
Other:
1.5. Participation: Social Support Questionnaire (F-SozU: modified part B)
1.6. Pain: body chart, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
1.7. Cognition: Nuremberg Aging Inventory (NAI), subcategory: repeating numbers
Economic evaluation:
1.8. Health related quality of life: EuroQol (EQ-5D)
1.9. Evaluation of additional therapies, inpatient stays, and support by care services

2. Caregiver-related measures (if existing):
2.1. ** Depressive symptoms: Centre for Epidemiological Studies – Depression Scale (CES-D)
2.2. ** Sense of competence: Sense of competence questionnaire – short version (SCQ - subscale 2: self-efficacy)
2.3. ** Negative problem orientation: Social Problem-Solving Inventory – Revised (SPSI-R, subscale negative problem orientation)
2.4. ** Subjective physical symptoms: Giessen Subjective Complaints List (GBB-24, subscale pain in the limbs)
2.5. ** Leisure time satisfaction: Leisure time satisfaction (LTS, subscale frequency)
2.6. ** External assessment of behavioral problems of the patient: Revised Memory and Behaviour Problems Checklist (RMBPC, subscale frequency)
Economic evaluation:
2.7. ** Subjective health related quality of life: Carer-related quality of life questionnaire (Carer-Qol)
2.8. Evaluation of additional therapies, inpatient stays
2.9. Informal nursing / care activities

Measured at: T1a (at the end of the rehabilitation), T1b (at home, after rehabilitation), T2 (after the 4-month program), T3 (follow-up; three months after completion of the program)
* only measured at T1a and T3
** Not measured at T1a

In addition: interventional costs (economic evaluation)

Overall study start date
01/02/2015

Overall study end date
17/09/2018

Eligibility

Participant inclusion criteria
Inclusion criteria patients:
1. Hip or pelvic fracture if not older than 3 months
2. Community-dwelling

3. 4 m independent walking with walking aid
4. Age: 65 years and older
5. Cognitive impairment defined by having a Mini-Mental State Examination (MMSE) score of 17-26
6. Visual acuity: Snellen fraction ≥20/400

Inclusion criteria caregivers:
1. Supports patient ≥ 10.5 hours per week (informal care in ADL, IADL, and supervision)
2. The support is not commercial
3 ≥ 18 years of age
4. Willing to attend a personal consultation at the patient's home

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
240

Participant exclusion criteria
Exclusion criteria patients:
1. Delirium,
2. Severe somatic or mental disease, which doesn’t allow participation,
3. Patient is not able to understand and speak German,
4. No telephone available
5. Place of domicile not reachable by public transport in the region of the study center Stuttgart or >50 km away from the study center Heidelberg,
6. Assessment T1b cannot be conducted at the person´s home in week 1-6 after rehabilitation,
7. Moderate to severe aphasia (amnestic aphasia is not an exclusion criteria) or severe apraxia of speech, 8. Progressive, terminal status,
9. Insufficient hearing ability to conduct phone calls

Exclusion criteria caregivers:
1. Current mental illness or cognitive impairment that affects the ability to understand the requirements of the assessments, to participate in the intervention or to give informed consent
2. No telephone available
3. Insufficient hearing ability to conduct phone calls
4. Not able to understand and speak German

Recruitment start date
27/07/2015

Recruitment end date
30/06/2018

Locations

Countries of recruitment
Germany

Study participating centre
Robert Bosch Hospital, Clinic for Geriatric Rehabilitation, Dr. Klaus Pfeiffer (recruiting center, module 1)
Auerbachstr. 110
Stuttgart
Germany
70376

Study participating centre
Agaplesion Bethanien Hospital gGmbH, Geriatric Center at the University of Heidelberg, Prof. Dr. Klaus Hauer (recruiting center, module 1)
Rohrbacher Str. 149
Heidelberg
Germany
69126

Study participating centre
Mannheim University of Applied Science, Department of Social Work, Prof. Dr. Martina Schäufele (module 2)
Paul-Wittsack-Str. 10
Mannheim
Germany
68163

Sponsor information

Organisation
Robert Bosch Gesellschaft für Medizinische Forschung mbH (RBMF), executive center: Robert Bosch Hospital

Sponsor details
Auerbachstr. 112
Stuttgart
Germany
70376

Sponsor type
Research organisation

Website
http://www.rbk.de/

ROR
https://ror.org/01fe0jt45

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

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
Study protocol to be submitted September 2017
Study results 2019/2020
Subgroup analyses 2020
There are further specific analyses planned but not scheduled yet

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
After the trialists have published the primary and secondary outcomes a controlled access for interested study groups in this field for further or shared data analyses will be possible with the consent of the study investigators. In any case an additional positive ethics vote will be mandatory prior to data sharing and further analyses. Study data will be stored after the study at the University of Ulm (Institute of Epidemiology & Medical Biometry, Ulm University, Prof. Dietrich Rothenbacher).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/04/2019	02/05/2019	Yes	No