Trial Description

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

Trial Acronym

PROFinD 2

URL of the trial

http://www.profind.info/

Brief Summary in Lay Language

Hip and pelvic fractures are among the most serious fall-related injuries. Particularly in persons with cognitive impairment, the risk of being injured, becoming dependent on care and mortality rises. However, there is a lack of specific recommendations for the treatment after rehabilitation in cognitively impaired patients with hip or pelvic fractures. In this study, we examine the effects of a 4-month program for this patient group after rehabilitation. The program comprises two modules: Module 1 “physical exercise”: supervised motor training (2 x per week at the patients´ homes), independent home training, activity promotion; Module 2: “Counseling”: counseling for patients as well as for informal caregivers, if existing. Module 1 is implemented by physiotherapists / sports scientists and volunteer instructors. Module 2 is implemented by social workers. Participants receiving the program (intervention group) are compared to a control group. The control group receives the standard rehabilitation (i.e., standard training in rehabilitation, standard after-care, and additional information about physical training). The intervention group additionally receives the 4-month program. We want to examine, if participants of the intervention group significantly improve their physical activity and functional performance as compared to the control group. Additionally, the situation of informal caregivers (e.g., depressive symptoms, physical complaints) and the costs of the program are evaluated. The objective of the study is to improve the care of cognitively impaired patients with hip / pelvic fractures in the transition from rehabilitation to their homes.

Brief Summary in Scientific Language

Hip and pelvic fractures are among the most serious fall-related injuries and represent the leading cause for hospitalization among people over 65 years of age. With a concurrent cognitive impairment, the risk of care dependency and mortality rises. To date, no study investigated the effects of a specific intervention program for patients with hip / pelvic fracture and cognitive impairment in the homely environment after rehabilitation. Thus, the aim of this study is to examine the effects of a 4-month multifactorial intervention to improve the care for this patient group. As a secondary issue, the situation of informal caregivers (if existing) will be evaluated. 240 older persons (≥65 years) with fall-

related hip or pelvic fractures and incipient to moderate cognitive impairments (Mini Mental State Examination: 17-26) will be randomly assigned into an intervention and a control group. Participants in the control group receive standard care (standard rehabilitation, possibly standard outpatient care after discharge, additional information about physical training at the end of rehabilitation). Participants in the intervention group will additionally complete a 4-month multifactorial intervention to increase physical activity and improve functional performance (Module 1 “physical exercise”: training 2 times per week [balance, walking, strength] supervised by a volunteer instructor [3 home visits by volunteer instructor together with a professional instructor], unsupervised home training, activity promotion; Module 2 “Counseling”: care counseling with a focus on promotion of activity and participation (modified Care Counselling Inventory – CCI; Hendlmeier et al. 2014) for all participants and specific counseling for informal caregivers, if existing (problem solving and education; D’Zurilla, T. J., & Nezu, A. 2006; Pfeiffer et al. 2014). Counseling comprises one home visit and telephone contacts. Measurements will be implemented at the end of the rehabilitation (T1a); at home, after the end of the rehabilitation (T1b); after the 4-month program (T2); and three months later (T3, “follow-up”). Primary outcomes are physical activity and functional performance. Secondary patient-related outcomes are fall-related self-efficacy, fear of falling, falls, activities of daily living, quality of life, and depressive symptoms. Additionally, the variables pain, social support and cognition are evaluated. Secondary caregiver-related outcomes (if existing) are depressive symptoms, care-related self-efficacy, negative problem orientation, subjective physical complaints, leisure time activities, and behavioral problems of the patient. An economic evaluation of the intervention will be conducted. It is assumed that the routine care in combination with the multifactorial intervention positively affects physical activity, functional performance and all other secondary variables as compared to standard care.

References:
Hendlmeier, I., Hoell, A., Schäufele, M. (2014a). Das Pflegeberatungsinventar (PBI). Assessment für die qualifizierte Pflegeberatung (Selbstauskunft).

D’Zurilla, T. J., & Nezu, A. (2006). Problem-solving therapy: A positive approach to clinical intervention (3rd ed.). New York, NY: Springer.

Pfeiffer K, Beische D, Hautzinger M, Berry JW, Wengert J, Hoffrichter R, Becker C, van Schayck R, Elliott TR. Telephone-Based Problem-Solving Intervention for Family Caregivers of Stroke Survivors: A Randomized Controlled Trial. J Consult Clin Psychol. 2014; 82(4): 628–643.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00008863**
- Date of Registration in DRKS: **2015/07/17**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **150/2015BO1 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

Health condition or Problem studied

- Free text: **Hip / pelvic fracture**
- ICD10: **S72.0 - Fracture of neck of femur**
- ICD10: **S72.1 - Pertrochanteric fracture**
- ICD10: **S72.2 - Subtrochanteric fracture**
- ICD10: **S32.1 - Fracture of sacrum**
- ICD10: **S32.2 - Fracture of coccyx**
- ICD10: **S32.3 - Fracture of ilium**
- ICD10: **S32.4 - Fracture of acetabulum**
- ICD10: **S32.5 - Fracture of pubis**
- ICD10: **S32.7 - Multiple fractures of lumbar spine and pelvis**
- ICD10: **S32.8 - Fracture of other and unspecified parts of lumbar spine and pelvis**
- Free text: **Incipient- to moderate-stage cognitive impairment (Score Mini Mental State Examination: 17-26)**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Intervention group:
  - Standard inpatient rehabilitation with training
  - 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
  - Information about the program
  - Usual non-controlled care including physiotherapy, if prescribed by attending physician

after discharge

- 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 discharge:
- Information about the intervention after randomization; training starts after the assessment T1b
- Assessment of mobility and independency, definition of mobility and participation goals, introduction of the VI, provision and introduction of and 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
- 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 in home visits), maximum duration of a visit is 2 hours
- Unsupervised home training, 1 - 4 times per week for approx. 10-20 minutes, depending on the capacity of the patient and caregiver support
- Initial home visit (maximum duration: 2 hours) and 2 additional home visits (EI + VI)
- 5 telephone calls (EI)

Module 2: Care counseling with a focus on promotion of activity and participation (duration: 3.5 months)
- Implemented by social worker
- Starts 1-4 weeks after the first home visit by the EI

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

Informal caregiver (if existing):
- 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)
- Caregiver's role in the implementation of mobility and participation goals of the patient
- 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.
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- Arm 2: **Control group:**
  - Standard inpatient rehabilitation with appropriate training
  - 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
  - Usual non-controlled care including physiotherapy, if prescribed by attending physician after discharge

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***

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Study Type Non-Interventional: **[---]***

- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Other**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Patient-related measures:
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-u; three months after completion of the program)

2. Physical Performance
- Short Physical Performance Battery (SPPB; DynaPort)

Measured at: T1a (at the end of the rehabilitation), T1b (at home, after rehabilitation), T2 (after the 4-month program), T3 (follow-u; three months after completion of the program)

Secondary Outcome

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)
- **Falls: Falls diary / weekly telephone call
- Depressive symptoms: Montgomery-Asberg Depression Scale (MADRS)
- Activities of daily life: *Barthel-Index, and **study specific questions
- Health related quality of life: **Quality of Life in Alzheimer's Disease (Qol-AD)
Other:
- Participation: Social Support Questionnaire (F-SozU: modified part B)
- Pain: body chart, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
-Cognition: Nuremberg Aging Inventory (NAI), subcategory: repeating numbers
Economic evaluation:
- Health related quality of life: EuroQol (EQ-5D)
- Evaluation of additional therapies, inpatient stays, and support by care services

2. Caregiver-related measures (if existing):
- ** Depressive symptoms: Centre for Epidemiological Studies – Depression Scale

(CES-D)
- ** Sense of competence: Sense of competence questionnaire – short version (SCQ - subscale 2: self-efficacy)
- ** Negative problem orientation: Social Problem-Solving Inventory – Revised (SPSI-R, subscale negative problem orientation)
- ** Subjective physical symptoms: Giessen Subjective Complaints List (GBB-24, subscale pain in the limbs)
- ** Leisure time satisfaction: Leisure time satisfaction (LTS, subscale frequency)
- ** External assessment of behavioral problems of the patient: Revised Memory and Behaviour Problems Checklist (RMBPC, subscale frequency)
Economic evaluation:
- ** Subjective health related quality of life: Carer-related quality of life questionnaire (Carer-Qol)
- Evaluation of additional therapies, inpatient stays
- 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-u; three months after completion of the program)

*** only measured at T1a and T3**
**** Not measured at T1a**

In addition: interventional costs (economic evaluation)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Robert-Bosch-Krankenhaus, Abteilung für Geriatrie und Klinik für Geriatrische Rehabilitation, Stuttgart**
- Medical Center **Agaplesion Bethanien Krankenhaus gGmbH, Geriatrisches Zentrum an der Universität Heidelberg, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/27**
- Target Sample Size: **240**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Inclusion criteria patients: (1) hip or pelvic fracture during the last 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

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 T1 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

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/09/17**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*