Trial Description

Title

Project to implement an adequate pain management in nursing homes

Trial Acronym

PIASMA

URL of the trial

[---]*

Brief Summary in Lay Language

Up to 80% of nursing home residents experience pain at rest or pain on exertion. The prevalence of pain is rather high in residents who are able to communicate their pain but also in those who are not able to communicate or report pain (i.e. residents with progressed dementia, primarily). Especially nurses, who take an active and time-consuming part in everyday care, face the challenge to provide an adequate care of pain for residents, including end-of-life phases. Next to the specific knowledge and competencies regarding pain management strategies, special attention has to be given to the provision of palliative care structures and supply. It is evident that resident-targeted interventions in terms of nursing pain management incorporating palliative care are of essential importance. One can assume that such interventions are necessary to enable an optimal and high-quality care of nursing home residents regardless of residents ability to self-report pain or not. The PIASMA project aims to improve the pain situation fo residents in nursing homes. The focus lies on an analysis of the received pain management in place today and the pain situation of residents, the subsequent identification of areas requiring optimisation and the changes gradually resulting from a systemic intervention. In addition, it will be analysed to what extent palliative care needs are being included in applied nursing.

Primarily, the forthcoming research questions are pursued:

Brief Summary in Scientific Language

Background.
The pain situation of residents of nursing homes represents a huge challenge in nursing and medical care not least due to the continuously high prevalence (Kalinowski et al., 2015). In German nursing homes a prevalence of pain of approx. 49% at rest and 67% on exertion must be assumed (Dräger et al., 2012; Lukas, Mayer, Onder, Bernabei, & Denkinger, 2015; Osterbrink et al., 2012). In addition to the burden for the individuals, untreated or insufficiently treated pain is also an economic burden (Dietl & Korczak, 2011). Especially the increasing number of residents of nursing homes suffering from various degrees of dementia entails

new challenges for pain management. Next to the indisputable necessity of the adaption of instruments and pain assessment and documentation procedures against the background of different degrees of residents' cognitive function it is furthermore evident that nursing homes have a special need for palliative care concepts (Becker-Ebel et al., 2012; Gerhard & Bollig, 2007; Knipping, 2007; Kojer & Schmidl, 2011).

Rationale and aims.
The PIASMA project aims to optimise multiprofessional pain management by integrating palliative care structures and concepts in the nursing homes (operator: Curanum AG) in Bavaria. The primary focus lies on an analysis of the received pain management in place today and the pain situation of residents, the subsequent identification of areas requiring optimisation and the changes gradually resulting from a systemic intervention. In addition, it will be analysed to what extent palliative care needs are being included in applied nursing, what percentage of residents die in nursing homes and what kind of palliative care measures are being carried out.

Design, methods and data collection.
As part of the cluster randomised controlled pre-test post-test intervention trial in 20 nursing homes (ten control and ten intervention facilities) structural data (assessment form on aggregated regulations, procedures, records on pain and palliative care mechanisms) and resident-specific documents (care records, medical characteristics, palliative care indicators) will be collected, the residents will be examined according to their cognitive skills (self-assessment/external assessment) and certified nurses will be interviewed online. The resident-specific data collection will be conducted by specifically trained study assistants.

Intervention.
The 12-month intervention phase includes advanced training for and the systematic implementation of pain nurses and pain care assistants, web-based training on chronic pain and dementia for nurses and, if necessary, GPs, the implementation of/instructions for the creation of treatment plans, resident-specific pain assessment mechanisms and the palliative care tool SPICT-DE for identifying residents potentially requiring palliative care as well as the implementation of interdisciplinary quality circles and specific expert training on 'pain management' and 'palliative care'.

Time flow.
The initial data collection (pretest t0) will take place from November 2016 to April 2017. The intervention package will be implemented—successively planned for every nursing home—from April 2017 to February 2018. Consequently, the second data collection (posttest t1) will be conducted from November 2017 to April 2018. After completion of the trial, the interventional package will be implemented in all Bavarian Curanum AG facilities.

Organizational Data

- DRKS-ID: **DRKS00011062**
- Date of Registration in DRKS: **2016/10/20**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **379-16 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1187-3174**

Health condition or Problem studied

- Free text: **Pain situation of old and oldest old nursing home residents with different degrees of cognitive impairment (i.e. early and later stages of dementia)**
- ICD10: **R52.0 - Acute pain**
- ICD10: **R52.1 - Chronic intractable pain**
- ICD10: **R52.2 - Other chronic pain**
- ICD10: **R52.9 - Pain, unspecified**
- ICD10: **F45.41 - [generalization F45.4: Persistent somatoform pain disorder]**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>To assess the cognitive function of the nursing home residents, the Mini-Mental-State-Examination (MMSE) is used as the initial screening (Folstein, Folstein, & Fanjiang, 2001; Folstein, Folstein, & McHugh, 1975). Residents with MMSE-scores between 18-30 points are stratified as residents with no or mild cognitive impairment, those with MMSE-scores between 10-17 as residents with moderate cognitive impairment, and those with MMSE-scores between 0-9 as residents with severe cognitive impairment (Basler, 2007; Ivemeyer & Zerfaß, 2006). Within the respective study, two subsamples of nursing home residents are realized: Nursing home residents with a MMSE-score ranging from 10 to 30 points (assumed to be able to provide self-report) and nursing home residents with a MMSE-score ranging from 0-9 points (assumed not to be able to provide self-report). The first subsample will be surveyed with standardized questionnaires, the second group will be examined using standardized observational assessment tools.

  Cluster randomised controlled trial (1:1 Intervention/Control): 10 nursing homes intervention group (Sampling frame 'intervention': approx. 1,100 residents)

  The intervention will comprise:

  •Adaption and/or preparation of written instructions
  •Online-based training for nurses regarding chronic pain
  •Training and implementation of Pain Nurses and Pain Care Assistants
  •Implementation of/instructions for the creation of treatment plans, resident-specific pain assessment mechanisms and the palliative care tool SPICT-DE
  •Implementation of interdisciplinary quality circles
  •Specific expert training on
  a) acceptable pain situation
  b) treatment plan

- Arm 2: **Cluster randomised controlled trial (1:1 Intervention/Control): 10 nursing homes control group (Sampling frame 'control': approx. 1,100 residents)**

  Control: Care 'as usual' without intervention (normal treatment procedures)

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

A. The primary outcomes for residents able to perform self-assessment are the average pain intensity as maximum pain during the previous 24 hours, measured by means of the Numeric Rating Scale (NRS-11) as well as the percentage of residents who according to self-assessment report a stable pain situation and/or whose pain situation is marked as stable in the care records.
Primary outcomes (residents able to perform self-assessment):
- Pain intensity (maximum pain) (NRS-11) in terms of the Brief Pain Inventory (BPI) (Cleeland (1982); German version Radbruch et al. (1999); German, modified and validated nursing home version Budnick et al. (2016))
- Percentage of residents with documented (care records) or self-reported 'stable pain situations'

B. The primary outcome for residents unable to perform self-assessment is the amount of pain indicators collected by means of external assessment, measured according to Pain Assessment in Advanced Dementia (PAINAD) as well as the percentage of residents with stable pain situations according to external assessment performed by the nurses and/or whose pain situations are marked as stable in the care records.
Primary outcomes (residents not able to perform self-assessment):
- Cutoff>1 (relevant signs of pain) in terms of Pain Assessment in Advanced Dementia (PAINAD) (Warden, Hurley & Volicer (2003); German validated version Basler et al. (2006) and Schuler (2007))
- Percentage of residents with documented (care records) 'stable pain situations'
- Short-form questionnaire 'Surprise Question' (Moroni et al., 2014) as a proxy instrument rated by the nurses to screen the individual residents' palliative care requirements

Secondary Outcome

A. Secondary outcomes and controls in the sample of residents who are able to

perform self-assessment:
- Aggregated characteristics of nursing home structure (e.g. ratio nurses:residents, single/shared room)
- Regulations regarding pain therapy and palliative care (e.g. documentation forms, guidelines, procedures, palliative care concepts)
- Online-CASI of nurses regarding selected topics of pain management in those residents who are able to perform self-assessment
- Resident-specific sociodemographic, biometrical, nursing and medical characteristics from the electronic care records
- Scale physical and psychic pain interference in terms of the Brief Pain Inventory (BPI)
- EQ-5D-3L (The EuroQol Group, 1990; German version Oct. 2014)
- Geriatric Depression Scale (GDS-SF15) ((Yesavage et al., 1983); German version Gauggel & Birkner (1999) and validated in nursing homes by Allgaier et al. (2011))

B. Secondary outcomes and controls in the sample of residents who are not able to perform self-assessment:
- Aggregated characteristics of nursing home structure (e.g. ratio nurses:residents, single/shared room)
- Regulations regarding pain therapy and palliative care (e.g. documentation forms, guidelines, procedures, palliative care concepts)
- Online-CASI of nurses regarding selected topics of pain management in those residents who are not able to perform self-assessment (Pretest: 15/11-30/12/2016)
- Resident-specific sociodemographic, biometrical, nursing and medical characteristics from the electronic care records
- Neuropsychiatric Inventory (NPI-NH) (Cummings (1996, 1997; 1994); German NPI-NH Mapi Research Trust (2006), validated by Reuther et al. (2016))

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **15 Altenheime (Nursing Homes), Bayern (Bavaria)**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/02/01**
- Target Sample Size: **460**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Gender: **Both, male and female**

- Minimum Age: **60 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Aged 60 or older, living permanently in the nursing home, written informed consent

Exclusion criteria

Short-term care and day care, congenital/permanent multi-handicap, insufficient knowledge/ability of German language (self-report), acute ailments, excessive impairment of the general state of health, life-threatening situations

Addresses

- **Primary Sponsor**

  Curanum AG
  Zirkus-Krone-Str. 10
  80335 München
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.korian.de**

- **Contact for Scientific Queries**

  Institut für Pflegewissenschaft und -praxis
  Mr. Mag. Patrick Kutschar
  Strubergasse 21
  5020 Salzburg
  Austria

  Telephone: **0043662242080344**
  Fax: **[---]***
  E-mail: **patrick.kutschar at pmu.ac.at**
  URL: **[---]***

- **Contact for Public Queries**

  Institut für Pflegewissenschaft und -praxis, Paracelsus Medizinische Privatuniversität
  Ms. Mag. Denise Seidenspinner, MScN

Contact for Public Queries

Institut für Pflegewissenschaft und -praxis, Paracelsus Medizinische Privatuniversität
Ms. Mag. Denise Seidenspinner, MScN
Strubergasse 21
5020 Salzburg
Austria

Telephone: **00491771802583**
Fax: **[---]***
E-mail: **denise.seidenspinner at pmu.ac.at**
URL: **[---]***

■ **Contact for Scientific Queries**

Institut für Pflegewissenschaft und -praxis
Dr. Irmela Gnass
Strubergasse 21
5020 Salzburg
Austria

Telephone: **00436622402080344**
Fax: **[---]***
E-mail: **irmela.gnass at pmu.ac.at**
URL: **[---]***

■ **Collaborator, Other Address**

Curanum AG
Zirkus-Krone-Str. 10
80335 München
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.korian.de**

Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Paracelsus Medizinische Privatuniversität
5020 Salzburg
Austria

Telephone: **[---]***
Fax: **[---]***

Institutional budget, no external funding (budget of sponsor/PI)

Paracelsus Medizinische Privatuniversität
5020 Salzburg
Austria

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

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Curanum AG
80335 München
Germany

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

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

Land Salzburg
5020 Salzburg
Austria

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/04/26**

Trial Publications, Results and other documents

- Background literature **Siehe "PIASMA_Hintergrundliteratur"**

** 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.*