# Trial Description

## Title

**"PROCARE-prevention in stationary care facilities"- prevention program for caregivers**

## Trial Acronym

**PROCARE**

## URL of the trial

**[---]***

## Brief Summary in Lay Language

**Nurses working in the field of elderly care are known to be especially burdened by different situations in their daily work, e.g. lifting and carrying of the elderly and the handling of mentally confused and aggressive patients. Research has shown that those working situations lead to higher stress levels and diseases of the back muscles and bones. Other scientific studies found that physical activity programs are able to reduce these back problems.**
**This program "PROCARE – prevention in stationary care facilities" aims at determining which working situations are causing burden for the elderly care nurses and what their current health status is, as well as how physical activity programs should be designed in order to be helpful and of interest for the nurses working in nursing homes.**
**Furthermore, we conduct a 22 week physical activity program which focuses on posture training and back-fitness. Posture training takes place once a week for a period of 20 to 30 minutes (for 10 weeks). It includes the learning of different techniques, in order to deal with physically challenging situations at the work place. The back-fitness program (for 12 weeks) includes the components mobility, coordination, strength and relaxation. Strength training is divided into 3 phases, each lasting 4 weeks. An increase in load is planned in each phase.**
**To obtain a verifiable structure, the program was divided as follows:**

**1. mobility training (5-10 minutes)**
**2. coordination training (10-15 minutes)**
**3. strength training (30-40 minutes)**
**4. relaxation (5-10 minutes)**

**The effects of this program on back pain and the general health status are assessed. Other training programs are designed after the intervention program, according to the individual wishes of the nurses working in each nursing home that takes part in the study.**
**The study design was adopted according to the study DRK S00015249, which received a positive ethics vote (2018_168, Ethikkomission Universität Hamburg).**

## Brief Summary in Scientific Language

**The demographic change causes increasing numbers of elderly, who are increasingly bedridden (Statistisches Bundesamt 2017). Moreover, an average**

**number of 27.5 days of inability to work per employee were documented in 2015 in the healthcare sector (Badura et al. 2016). Burdens resulting from heavy lifting and carrying are among the reasons for the inability to work (Jenull-Schiefer et al. 2007) as well as psycho-sociological factors that emerge from e.g. handling mentally disturbed and aggressive patients (Demir et al. 2003), the death of patients and limited rehabilitation results (Jenull-Schiefer et al. 2007). Backpain occurs in 80-85 % of all geriatric nurses and are often correlated to a high psycho-social workload (Karahan et al. 2009). Research has shown that frequently performed transferring tasks when pressed for time and in unfavorable postures (e.g. turning and holding patients) cause lumbar tissue damage and backpain (Seidler et al. 2011; Eriksen 2004). Furthermore, the efficacy of combinational exercise programs (training in ergonomics combined with strength and flexibility training) to reduce back trouble has been proven (Gauthier et al. 2015). To the backdrop of these findings, the project “PROCARE - Prävention in stationären Pflegeeinrichtungen” (prevention in stationary care facilities) is determined to identify physical and psychological burdens and requirements of geriatric nurses, their health status and working atmosphere, their work related behavioral and experiential patterns as well as their general needs but also the obstacles that inhibit them from participating in prevention programs. The analysis of all this information will enable the executing staff of PROCARE to derive prevention measures, to implement them and to reevaluate the outcome. Furthermore, we conduct a 22 week physical activity program which focuses on posture training (Wollesen, Lex & Mattes 2012) and back-fitness. Posture training takes place once a week for a period of 20 to 30 minutes (for 10 weeks). It includes the learning of different techniques, in order to deal with physical stress at the work place and be able to compensate in a stress-compatible manner.The back-fitness program (for 12 weeks) includes the components mobility, coordination, strength and relaxation. Strength training is divided into 3 phases, each lasting 4 weeks. An increase in load is planned in each phase.**
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## Organizational Data

- DRKS-ID: **DRKS00015241**
- Date of Registration in DRKS: **2018/08/09**
- 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.: **2018_168 , Lokale Ethikkommission Universität Hamburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **M00-M99 - Diseases of the musculoskeletal system and connective tissue**
- ICD10: **Z73 - Problems related to life-management difficulty**

## Interventions/Observational Groups

- Arm 1: **ergonomics and posture training, 10 weeks, 20-30 minutes per week**
- Arm 2: **ergonomics and posture training, 10 weeks, 20-30 minutes per week; back fitness, 12 weeks, 45-60 minutes per week**

## Characteristics

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

### Primary Outcome

**In the randomized controlled trial, questionnaire data are collected at four measurement points (pre-intervention, post-intervention (10 weeks), post-intervention (22 weeks) and follow-up measurements after 34 weeks.
The primary outcome measures include the following parameters:
Workplace stress factors (Questionnaire for Subjective Assessment of Workplace Exposure according to Slesina; Slesina 2009), Musculoskeletal Complaints (Questionnaire on Musculoskeletal Complaints - Nordic questionnaire; Caffier et al. 1999), Physical and Psychological Sum Score (Health Condition Questionnaire-SF12; Bullinger et al. 1995), Sum Score on Chronic Stress (Trier Inventory on Chronic Stress-TICS; Schulz & Schlotz 1999), Work-related Behaviour and Experience Patterns (Questionnaire on Work-related Behavior and Experience Patterns-AVEM; Schaarschmidt & Fischer 2008).**

### Secondary Outcome

**In the randomized controlled trial, questionnaire data are collected at four measurement points (pre-intervention, post-intervention (10 weeks), post-intervention (22 weeks) and follow-up measurements after 34 weeks.
The secondary endpoints include the following parameters: Personal resources (nutritional behavior, sports behavior, state of health), presentism, wishes and obstacles regarding an exercise program and work atmosphere.
These are self-developed questionnaires.**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- other **Pflegeeinrichtungen, Hamburg**
- other **Pflegeeinrichtungen, Bremen**
- other **Pflegeeinrichtungen, Paderborn**
- other **Pflegeeinrichtungen, Chemnitz**
- other **Pflegeeinrichtungen, Stuttgart**
- other **Pflegeeinrichtungen, Karlsruhe**
- other **Pflegeeinrichtungen, Erlangen**
- other **Pflegeeinrichtungen, Frankfurt a.M.**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/08/13**
- Target Sample Size: **700**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**The (pre-post) intervention study includes all employees of care facilities.**

### Exclusion criteria

**no exclusion criteria**

## Addresses

- **Primary Sponsor**

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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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## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

## 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.*