PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Evaluation of Effectiveness of Ambulatory Geriatric Rehabilitation

Trial Acronym

EAGER

URL of the trial

[---]*

Brief Summary in Lay Language

Due to demographic developments the proportion of elderly and multimorbid people at risk for nursing home admission or progression to higher nursing care levels is increasing. Consequently, a need to prevent, minimize or delay long term nursing care for elderly has been recognized. Preventive ambulatory geriatric rehabilitation (AGR) offers a community based outpatient intervention program to prevent falls and increase patient safety, thereby avoiding hospitalisation and institutionalisation of elderly at risk. The aim of the study is to evaluate the effectiveness of AGR from the patients' perspective with respect to patient safety related parameters as well as from the health insurance perspective regarding cost and treatment related parameters.

Brief Summary in Scientific Language

Due to demographic developments the proportion of elderly and multimorbid people at risk for nursing home admission or progression to higher nursing care levels is increasing. Consequently, a need to prevent, minimize or delay long term nursing care for elderly has been recognized. Preventive ambulatory geriatric rehabilitation (AGR) offers a community based outpatient intervention program to prevent falls and increase patient safety, thereby avoiding hospitalisation and institutionalisation of elderly at risk. The aim of the study is to evaluate the effectiveness of AGR from the patients' perspective with respect to patient safety related parameters as well as from the health insurance perspective regarding cost and treatment related parameters. This objective is mainly accomplished by the use of claims data comparing treated and untreated patients with appropriate techniques to reduce confounding and bias. Propensity score techniques will be used to improve inferences on average treatment effects based on claims data. 4 controls will be matched to one AGR patient. A range of regression models will be used, as appropriate, including time-to-event models and count data models.
On an explorative basis we will assess the impact of AGR comparing primäry clinical data before and after the intervention.

Organizational Data

- DRKS-ID: **DRKS00008926**
- Date of Registration in DRKS: **2015/07/29**
- 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.: **BB 077/14 , Ethikkommission an der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald**

Secondary IDs

Health condition or Problem studied

- Free text: **Progression of nursing care level, admission to nursing home, hospital admission, ambulatory nursing care, fractures and fall-related injuries (ICD-10-GM diagnosis codes: Sxx, Txx), multimorbidity**
- ICD10: **S02 - Fracture of skull and facial bones**
- ICD10: **S12 - Fracture of neck**
- ICD10: **S22 - Fracture of rib(s), sternum and thoracic spine**
- ICD10: **S32 - Fracture of lumbar spine and pelvis**
- ICD10: **S42 - Fracture of shoulder and upper arm**
- ICD10: **S52 - Fracture of forearm**
- ICD10: **S62 - Fracture at wrist and hand level**
- ICD10: **S72 - Fracture of femur**
- ICD10: **T02 - Fractures involving multiple body regions**
- ICD10: **T10 - Fracture of upper limb, level unspecified**
- ICD10: **T12 - Fracture of lower limb, level unspecified**
- ICD10: **T14.2 - Fracture of unspecified body region**
- ICD10: **S00 - Superficial injury of head**
- ICD10: **S01 - Open wound of head**
- ICD10: **S03 - Dislocation, sprain and strain of joints and ligaments of head**
- ICD10: **S06 - Intracranial injury**
- ICD10: **S11 - Open wound of neck**
- ICD10: **S20 - Superficial injury of thorax**
- ICD10: **S21 - Open wound of thorax**
- ICD10: **S30 - Superficial injury of abdomen, lower back and pelvis**
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ICD10: **S33 - Dislocation, sprain and strain of joints and ligaments of lumbar spine and pelvis**

- ICD10: **S40 - Superficial injury of shoulder and upper arm**
- ICD10: **S41 - Open wound of shoulder and upper arm**
- ICD10: **S43 - Dislocation, sprain and strain of joints and ligaments of shoulder girdle**
- ICD10: **S50 - Superficial injury of forearm**
- ICD10: **S51 - Open wound of forearm**
- ICD10: **S53 - Dislocation, sprain and strain of joints and ligaments of elbow**
- ICD10: **S60 - Superficial injury of wrist and hand**
- ICD10: **S61 - Open wound of wrist and hand**
- ICD10: **S63 - Dislocation, sprain and strain of joints and ligaments at wrist and hand level**
- ICD10: **S70 - Superficial injury of hip and thigh**
- ICD10: **S71 - Open wound of hip and thigh**
- ICD10: **S73 - Dislocation, sprain and strain of joint and ligaments of hip**
- ICD10: **T00 - Superficial injuries involving multiple body regions**
- ICD10: **T01 - Open wounds involving multiple body regions**
- ICD10: **T03 - Dislocations, sprains and strains involving multiple body regions**
- ICD10: **T11 - Other injuries of upper limb, level unspecified**
- ICD10: **T14 - Injury of unspecified body region**

Interventions/Observational Groups

- Arm 1: **Intervention group: Participation in the ambulatory geriatic programme (AGR) at one of the three participating rehabilitations centres in Mecklenburg-Vorpommern, Germany;**
  The programme spans 20 therapy days (2-3 therapy sessions per day), and typically lasts 4 weeks
- Arm 2: **(Matched) Control group: no AGR; many-to-one matching with presumably 4 controls for each AGR participant**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Non-randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Control group receives no treatment**

- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The main outcome comparing treated and untreated patients based on the claims data are progression of nursing care level, admission to nursing homes and ambulatory nursing care. Claims data from the health insurance fund AOK Nordost will be used.

The follow-up period is 4 quarters after the end of the AGR intervention period.

Secondary Outcome

Secondary outcomes are fractures, hospital admissions and inpatient days (per quarter), and costs from the health insurer perspective.On an exploratory basis we will assess the effects of AGR on different medical conditions using ICD-10 diagnosis codes and on mortality. Claims data from the health insurance fund AOK Nordost will be used.

Moreover we will analyse the changes, comparing clinical data before and after the intervention regarding mobility, self-dependence and cognitive performance using only the clinical data from AGR participants.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Mecklenburg-Pomerania**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2008/01/01**
- Target Sample Size: **900**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **70 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

The target population is defined by the eligibility requirements as stipulated by the statutory health insurance. The global criteria are: age >= 70 years, multimorbidity, impairment/handicap/functional deficits, and the presence of at least one of the following medical conditions based on ICD-10-GM diagnosis codes: I60 – I69, S72-, I70-, M16.-, M17.-, I50.-, J44.0, J44.1, J10 – J22, S00 – T98, M00 – M25, M45 – M51, I05 - I09, I20 – I25, G20.9, R29.5, R29.6, R29.8.

Exclusion criteria

Exclusion criteria include: i) living in a nursing home or receive home nursing care level III, ii) they need hospital care or inpatient treatment, iii) solely curative measures have been indicated, iv) regimens are too burdensome, v) severe clinical or musculoskeletal impairments that prevent active participation, or comorbidities and other complication that prevent active participation, vi) consent declined

Addresses

- **Primary Sponsor**

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  17475 Greifswald
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- **Contact for Scientific Queries**

  Abteilung für Allgemeinmedizin, Institut für Community Medicine, Universitätsmedizin Greifswald

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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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/12/31**

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **Studienprotokoll**
- Paper **Analyse klinischer Daten der AGKB Teilnehmer**
- Paper **Effekt der AGKB auf Polypharmazie und PIMs**

** 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.*