Trial Description

Title

Poly-stakeholders integrated care for chronic patients in acute phases

Trial Acronym

POLYCARE

URL of the trial

http://polycare-project.com

Brief Summary in Lay Language

Integrated care is a concept that focuses on establishing new organizational arrangements to better coordinate and integrate different forms of care provision by overcoming the still fragmented delivery of health and social services. However, there are still legal, organizational and structural barriers that hinder the implementation of integrated care. While in the past there have also been technical barriers, there are nowadays technical solutions available that can on the one hand help to bring the stakeholders together which are involved in patient's care and on the other hand provide medical surveillance for patients with acute medical conditions. This project aims to test and evaluate a service of fully integrated care in patients with acute medical conditions containing modules for communication, information-sharing, medical surveillance amongst other. The implementation will take place parallel to standard care and focuses on patients with acute but not critical medical conditions that can be treated at the patient´s home.
Key Objective of this study is the satisfaction and acceptance of the users (patients, relatives, nurses, doctors, social workers) with the provided service.

Brief Summary in Scientific Language

An ICT-supported application consisting of various components is to support all care providers (family doctors, nurses, social workers and relatives) of multimorbid patients in exacerbated disease situations with medical and social care and is to be evaluated afterwards.

Organizational Data

- DRKS-ID: **DRKS00014645**
- Date of Registration in DRKS: **2018/05/07**
- 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.: **20177240 , Ethikkommission der Ärztekammer Nordrhein**

DRKS-ID: **DRKS00014645**
Date of Registration in DRKS: **2018/05/07**
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.: **20177240 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

Health condition or Problem studied

- ICD10: **I50 - Heart failure**
- ICD10: **J44 - Other chronic obstructive pulmonary disease**
- ICD10: **J18 - Pneumonia, organism unspecified**
- ICD10: **N10 - Acute tubulo-interstitial nephritis**
- ICD10: **A46 - Erysipelas**

Interventions/Observational Groups

- Arm 1: **The target group of the study are chronically ill patients over the age of 65 years in acute medical situations. This is a pilot study in which the satisfaction and acceptance of the users (patients, relatives, nurses, doctors, social workers) with the provided services, here: the use of an app in the area of "Inegrated Care", is to be evaluated. Moreover, another aim of the study is to examine the usability of the system. The results are evaluated by various questionnaires.**
  The system is tested on the patient for 4-14 days and then evaluated using the questionnaires. In total, 30 patients are aimed to be enrolled until December 2018. The system includes an browser-based web app for the "Professionals", a mobile app on a tablet for the patient, as well as various measuring systems for vital signs (chest band, blood pressure, glucometer, sPO2 meter, balance), which are connected via Bluetooth with the mobile app.

Characteristics

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

Study Type: **Interventional**

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

- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health care system**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Evaluation of the ICT system with the System Usability Score (SUS)

Secondary Outcome

- Satisfaction of all users with the Polycare-service (eCCIS)
- Level of satisfaction of the patients regarding the devices (eCCIS)
- Number of patients who felt better supervised (questionnaire)
- Number of professional and informal carers who find the care provided by the service better/worse than usual (questionnaire)
- Level of satisfaction of Mobile App (patients) and Web App (formal and informal carers) (eCCIS)
- Level of satisfaction regarding the cooperation between the professional participants (questionnaire + focus group)
- Average of use of the devices (retroperspective analysis via system-queries)
- Frequency of accessing and duration of use of the Mobile App and Web App (Compliance) (analysis of the use of different components of the system)
- Retroperspective Identification of relevant changes in recorded vital signs not detected by the carers (system queries)
- Assessment of technical problems occurred at the patient’s home
- Number of alerts generated by the system regarding vital signs out of range (system queries)
- Number of alerts generated by the system regarding possible interactions in the medication plan (system queries)
- Improvement of quality of life during the project (EQ5D)
- Improvement of the Carer burden (Zarit)
- Improvement of Empowerment (PAM)
- Number of Hospitalizations during the project
- Assessment of the coordination between the stakeholders (focus group)
- Assessment of the impact (positive or negative) on the daily work for the professional carers (questionnaire)
- Assessment of the benefit of particular components of the system (questionnaire)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Linz, Troisdorf, Bad Honnef**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/09/04**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Age ≥ 65 years
• Living in the area of coverage
• Patients with the ability to follow study instructions and likely to attend and complete all required visits
• Written informed consent
Social:
• Supported by either a nursing service or an informal carer living in the same household
• Appropiate Housing Conditions
• Informal carer available (at least by telephone) all day
• Having social needs, defined as
• Barber at least 2 answers in the affirmative + Any Barthel-Score OR
• Barthel-Score between 80 and 95 + Barber at least 1 answer in the affirmative OR
• Barthel-Score 75 or less + any Barber
Medical:
COPD exacerbation (without indication for in-patient treatment according to the GP)
• physician-diagnosed COPD (defined as FEV1/ FVC <70%)
• new exertional dyspnea or worsening of existing exertional dyspnea
• necessity of a systemic therapy with antibiotics and/or corticosteroids
Decompensated heart failure (without indication for in-patient treatment

according to the GP)
• physician-diagnosed heart failure (all functional classes)
• At least one of the following symptoms
o new exertional dyspnea or worsening of existing exertional dyspnea
o new peripheral oedema or worsening of existing oedema
o increase in weight of ≥ 2 kg within 5 days or less
• necessity of new medication with a (additional) diuretic or modification (increase) of an existing diuretic therapy
Pneumonia (without indication for in-patient treatment according to the GP)
• Suspected pneumonia by the GP PLUS at least one of the following
o Corresponding auscultation of the lung
o Elevated CRP
o Corresponding Chest-x-ray
• At least two points in the Charlson Comorbidity Index (CCI)
Pyelonephritis (without indication for in-patient treatment according to the GP)
• Suspected pyelonephritis by the GP PLUS at least one of the following:
o Elevated CRP
o Corresponding urine test strip
o Corresponding ultrasound
• At least two points in the Charlson Comorbidity Index (CCI)
Erysipel (without indication for in-patient treatment according to the GP)
• Suspected erysipel by the GP
• At least two points in the Charlson Comorbidity Index (CCI)

Exclusion criteria

• Patients not able to give consent
• Necessity of hospitalization according to the appraisal of the GP
• Severe dyspnea
• Oxygen saturation < 90% (if measured)
• Rapid progression of symptoms
• Clouding of consciousness
• Central cyanosis
• Uncertain diagnosis
• Hypotension, defined as systolic blood pressure < 100 mmHg
• Pulmonary oedema
• New or hemodynamic relevant arrhythmias (including new atrial fibrillation)
• Patients without legal capacity who is unable to understand the nature, scope, significance and consequences of this clinical trial
• Patients with implanted pacemaker or ICD-system
• Patients with severe mental retardation, psychiatrical disorders or other cognitive impairment resulting in incapability to adequately estimate the risks and benefits of study participitation (e.g. advanced dementia)
• Patient lacks suitability for Polycare in estimation of the local Polycare-Team (consisting of staff of SZB and IfH of the UKB)

Addresses

■ **Primary Sponsor**

Universitätsklinikum Bonn - Studienzentrale SZB - Institut für klinische Chemie und klinische Pharmakologie
Mr. Dr. med. Martin Coenen

Primary Sponsor

Universitätsklinikum Bonn - Studienzentrale SZB - Institut für klinische Chemie und klinische Pharmakologie
Mr. Dr. med. Martin Coenen
Sigmund-Freund-Str. 25
53127 Bonn
Germany

Telephone: **+49228287116046**
Fax: **[---]***
E-mail: **martin.coenen at ukbonn.de**
URL: **https://www.studienzentrum-bonn.de/index.php?id=studienzentrale**

■ **Contact for Scientific Queries**

Uniklinik Bonn - Institut für Hausarztmedizin
Mr. Dr. med. Nils Heiland
Sigmund-Freund-Str. 25
53127 Bonn
Germany

Telephone: **+4922828714036**
Fax: **[---]***
E-mail: **nils.heiland at ukbonn.de**
URL: **www.hausarztmedizin-bonn.de**

■ **Contact for Public Queries**

Uniklinik Bonn - Institut für Hausarztmedizin
Mr. Dr. med. Nils Heiland
Sigmund-Freund-Str. 25
53127 Bonn
Germany

Telephone: **+4922828714036**
Fax: **[---]***
E-mail: **nils.heiland at ukbonn.de**
URL: **www.hausarztmedizin-bonn.de**

■ **Collaborator, Other Address**

Uniklinik Bonn - Institut für Hausarztmedizin
Mr. Prof. Dr. med. Klaus Weckbecker
Sigmund-Freund-Str. 25
53127 Bonn
Germany

Telephone: **+4922828711156**

Collaborator, Other Address

Uniklinik Bonn - Institut für Hausarztmedizin
Mr. Prof. Dr. med. Klaus Weckbecker
Sigmund-Freund-Str. 25
53127 Bonn
Germany

Telephone: **+4922828711156**
Fax: **[---]***
E-mail: **klaus.weckbecker at ukbonn.de**
URL: **www.hausarztmedizin-bonn.de**

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.)**

European Union- Horizon 2020
Avenue de Beaulieu 25
B-1160 Brüssel
Belgium

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/11/08**

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.*