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

Trial Description

Title

Evaluation of the projekt IKK IVP- Innovation, Medical Care, Patient

Trial Acronym

IKK IVP

URL of the trial

http://www.ikk-ivp.de

Brief Summary in Lay Language

Due to the sectoral separation between inpatient, rehabilitative and outpatient medical care that prevails in Germany, patients often experience delays in the course of their treatment. Therefore the IKK gesund plus in Saxony-Anhalt offers a personal service for patients with cardiological and neurological diagnoses. They will be supported during the treatment as well as in their home by a personal contact of the IKK gesund plus. The intervention is called IKK IVP innovation, care partner, patient. Patient coordinators and case managers in hospitals as new structural elements in the project accompany the care process of those and immediately organize all required measures. They also ensure that regulations and transfers are issued and approved promptly.
Five hypotheses are examined:
1. IKK IVP reduces the time between discharge from inpatient treatment or rehabilitation and the start of remedy supply (process level).
2. IKK IVP increases the proportion of patients with guideline-based medication (process level).
3. IKK IVP reduces the risk of re-events and deaths (result level).
4. IKK IVP reduces the risk of need for long-term care or assistance (result level).
5. IKK IVP increases patients' quality of life (result level).
The evaluation consists of two independent modules. In Module 1, a claims data analysis is performed. In module 2, a patient survey is carried out at two different points of time using a written questionnaire.
The evaluation of the IKK IVP project is based on a control group design.
The intervention group (IG) is formed by voluntary participants (insured persons living in Saxony-Anhalt) of the intervention programme (IKK IVP). Insured persons of the structurally similar statutory health insurance fund IKK classic with residence in the federal states of Saxony or Thuringia are serving as an external control group (extKG) with the aim of investigating the effectiveness of the programme in comparison to the IG. In addition, insured members of IKK gesund plus who do not participate in IKK IVP serve as internal control group (intKG).

Brief Summary in Scientific Language

Due to the sectoral separation between inpatient, rehabilitative and outpatient

medical care that prevails in Germany, patients often experience delays in the course of their treatment. The intervention project IKK IVP Innovation - Medical Care - Patient (IKK IVP; sponsor: Innovation Fund, funding code: 01NVF17039, duration: April 1, 2018 - March 31, 2021) of the statuory health insurance IKK gesund plus for insured residents of the federal state of Saxony-Anhalt aims at continuous, demand-oriented and cross-sectoral health care for patients with a serious acute disease (myocardial infarction, cerebrovascular disease, cerebral palsy, intracranial injuries, cardiac failure).
Five hypotheses are examined:
1. IKK IVP reduces the time between discharge from inpatient treatment or rehabilitation and the start of remedy supply (process level).
2. IKK IVP increases the proportion of patients with guideline-based medication (process level).
3. IKK IVP reduces the risk of re-events and deaths (result level).
4. IKK IVP reduces the risk of need for long-term care or assistance (result level).
5. IKK IVP increases patients' quality of life (result level).
Insured persons of the IKK gesund plus suffering from one of the mentioned index diseases form an intervention group, which receives a new form of care. The evaluation of the project consists of two modules. Both modules are based on the same control group design. Module 1 includes the analysis of claims data from outpatient and inpatient care, follow-up treatment, provision of drugs, remedies and aids as well as information on incapacity for work, need for care and reduced earning capacity of the insured persons. In Module 2, a patient survey is conducted to assess the quality of life and the need for help in working life and daily living of patients with one of the index diseases.
The intervention group (IG) is formed by voluntary participants (insured persons living in Saxony-Anhalt) of the intervention programme (IKK IVP). Insured persons of the structurally similar statutory health insurance fund IKK classic with residence in the federal states of Saxony or Thuringia are serving as an external control group (extKG) with the aim of investigating the effectiveness of the programme in comparison to the IG. In addition, insured members of IKK gesund plus who do not participate in IKK IVP serve as internal control group (intKG).

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00020510**
- Date of Registration in DRKS: **2020/03/26**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **59/18 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I21 - Acute myocardial infarction**
- ICD10: **I22 - Subsequent myocardial infarction**
- ICD10: **I60 - Subarachnoid haemorrhage**
- ICD10: **I61 - Intracerebral haemorrhage**
- ICD10: **I62 - Other nontraumatic intracranial haemorrhage**
- ICD10: **I63 - Cerebral infarction**
- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**
- ICD10: **I65 - Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction**
- ICD10: **I66 - Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction**
- ICD10: **I67 - Other cerebrovascular diseases**
- ICD10: **I68 - Cerebrovascular disorders in diseases classified elsewhere**
- ICD10: **I69 - Sequelae of cerebrovascular disease**
- ICD10: **G81 - Hemiplegia**
- ICD10: **G82 - Paraplegia and tetraplegia**
- ICD10: **G83 - Other paralytic syndromes**
- ICD10: **S06 - Intracranial injury**

Interventions/Observational Groups

- Arm 1: **The intervention group (IG) is formed by voluntary participants (insured persons living in Saxony-Anhalt) of the intervention programme. The patient coordinators receive optimized and needs-based care after acute illness.**
- Arm 2: **Insured members of IKK gesund plus who do not participate in IKK IVP or who were not offered the program serve as internal control group (intKG).**
- Arm 3: **Insured persons of the structurally similar statutory health insurance fund IKK classic with residence in the federal states of Saxony or Thuringia are serving as an external control group (extKG) with the aim of investigating the effectiveness of the programme in comparison to the IG.**

Characteristics

-

Study Type: **Interventional**

- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Five hypotheses are examined:
1. IKK IVP reduces the time between discharge from inpatient treatment or rehabilitation and the start of remedy supply (process level).
2. IKK IVP increases the proportion of patients with guideline-based medication (process level).
3. IKK IVP reduces the risk of re-events and deaths (result level).
4. IKK IVP reduces the risk of need for long-term care or assistance (result level).
5. IKK IVP increases patients' quality of life (result level).
The validity of hypotheses 1 to 4 can be evaluated using claims data from the statutory health insurance funds because they address scope, type, and amount of medical services. In Module 1, standardized claims data from the two statutory health insurance funds is used. The obligation to evaluate is laid down in the Social Code (SGB) V; the underlying data of the statutory health insurance funds is regulated in section 295 SGB V pp. In detail, this includes data on inpatient care (sect. 301 SGB V), services for medical rehabilitation as well as data about the supply of medicines (sect. 300 SGB V), therapeutic appliances and aids (sect. 302 SGB V). Data concerning the need for long-term care also will be used. In order to map the transition from inpatient to outpatient (follow-up) care after an acute event or rehabilitation, performance data from outpatient care (sect. 295 SGB V) is also used, with supplementary data on incapacity for work and reduced earning capacity for the subgroup of employed patients.
Module 2 aims to measure the quality of life (Hypothesis 4) and the assistance needs or limitations in everyday activities of patients suffering from one of the index diseases (Hypothesis 5). An interview will take place ten weeks after the occurrence of the disease and thus after the end of the acute treatment as well as a second time six months after discharge from hospital. The questionnaire consists of the Short-Form12 Health Survey Version 2 of the Socio-Economic Panel (SF12v2 of SOEP) to measure quality of life and of the Norwegian Function Assessment Scale (NFAS) for measuring physical and mental functioning in the working life and in daily living. In addition, the questionnaire contains further programme-specific items about participation in the IKK IVP project and personal details.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **IKK gesund plus, Magdeburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/06/01**
- Target Sample Size: **5000**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

The target group of the intervention, which began on 01.04.2018, are insured persons of the IKK gesund plus who have reached the age of 18 and are treated as in-patients with one of the main (index) diagnoses such as myocardial infarction, cerebrovascular disease or cerebral palsy and other paralysis syndromes as well as intracranial injuries:

G83 Other paralysis syndromes
S06 Intracranial injury (exception: without S06.0)

Exclusion criteria

/

Addresses

■ **Primary Sponsor**

IKK gesund plus
Mr. Andreas Köhler
Umfassungsstraße 85
39124 Magdeburg
Germany

Telephone: **0391 2806-1325**
Fax: **0391 2806-1329**
E-mail: **Andreas.Koehler at ikk-gesundplus.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Institut für Sozialmedizin und Gesundheitssystemforschung, Otto- von-Guericke-Universität Magdeburg, Medizinische Fakultät
Ms. Annemarie Feißel
Leipziger Straße 44
39120 Magdeburg
Germany

Telephone: **03916724309**
Fax: **03916124310**
E-mail: **annemarie.feissel at med.ovgu.de**
URL: **[---]***

■ **Contact for Public Queries**

IKK gesund plus
Mr. Andreas Köhler
Umfassungsstraße 85
39124 Magdeburg
Germany

Telephone: **0391 2806-1325**
Fax: **0391 2806-1329**
E-mail: **Andreas.Koehler at ikk-gesundplus.de**
URL: **[---]***

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.)**

  Gemeinsamer Bundesausschuss Innovationsfonds
  Gutenbergstraße 13
  10596 Berlin
  Germany

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

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.*