Trial Description

Title

Lifestyle Intervention in Chronic ischemic heart disease and Diabetes

Trial Acronym

LeIKD

URL of the trial

https://innovationsfonds.g-ba.de/projekte/neue-versorgungsformen/leikd-lebensstil-intervention-bei-koronarer-herzkrankheit-und-diabetes.115

Brief Summary in Lay Language

Chronic ischemic heart disease and diabetes mellitus type II have one of the highest morbidity and mortality rates in Germany. Especially in the presence of both diseases, these risks increase exponentially. The aim of this program is to reduce cardiovascular risk factors by promoting individual health literacy and a healthy lifestyle, thereby reducing the progress of the disease and the mortality of the patients.
Patients will receive individual exercise prescriptions and nutritional recommendations. This lifestyle intervention is accompanied by step counters, heart rate sensors, blood glucose meters and smartphones to allow regional implementation in different areas in Germany. In total, 1500 patients with diabetes mellitus type II and chronic ischemic heart disease will participate in the trial.
The project examines whether the intervention positively affects metabolic health and lifestyle behaviors, increases health literacy, and reduces cardiovascular events of these high risk patients. Furthermore it will be tested if the medical care for both urban and rural areas can be aligned.

Brief Summary in Scientific Language

Chronic ischemic heart disease and diabetes mellitus type II have one of the highest morbidity and mortality rates in Germany. Especially in the presence of both diseases, these risks increase exponentially. The combined endpoint of death and myocardial infarction is up to 30% within four years. A lifestyle intervention with exercise training and dietary change can reduce the mortality by 20-30% and is a class-I indication in the current guidelines of the EACP (European Association of Preventive Cardiology). Nevertheless, the implementation of lifestyle interventions in the population is insufficient.
This prospective randomized controlled trial examines whether a structured, individual and telemedicine-supported lifestyle intervention improves health literacy and reduces cardiovascular risk factors compared to a guideline-based recommendation (usual care). Furthermore it will be tested if the medical care for both urban and rural areas can be aligned.
In total, 1500 patients with diabetes mellitus type II and chronic ischemic heart disease will participate in the trial. The primary endpoint is a change in HbA1c after six months. Secondary endpoints include, amongst others, a change in health literacy, quality of life, daily physical activity, eating behavior and medical

care expenses as well as the number of major cardiovascular adverse events. After randomization (1:1), the 750 patients of the intervention group will receive individual exercise prescriptions and nutritional recommendations based on a maximum exercise stress test and a multi-day nutrition protocol. The intervention is accompanied by pedometers, heart rate sensors, blood glucose meters and smartphones as well as regular oral and written feedback.

Initial telephone contact with insured patients by health insurance company: 15/12/2018

anticipated first screening: 11/02/2019

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00015140**
- Date of Registration in DRKS: **2019/01/10**
- 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.: **144/18 S , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1217-6306**

Health condition or Problem studied

- ICD10: **I25 - Chronic ischaemic heart disease**
- ICD10: **E11 - Type 2 diabetes mellitus**

Interventions/Observational Groups

- Arm 1: **intervention phase 1 (week 1 – week 26): Telemedicine-supported lifestyle intervention trough individual structured exercise training (endurance and strength training), increase in daily physical**

activity, and individual nutritional recommendations, accompanied by regular oral and written feedback.

intervention phase 2 (week 27 – week 52):
Continuation of exercise training, daily physical activity and balanced diet without additional oral or written feedback. Patients receive a single feedback based on the results of the examination.

- Arm 2: **intervention phase 1 (week 1 – week 26):**
  general exercise and nutritional recommendations according to current guidelines

  intervention phase 2 (week 27 – week 52):
  general exercise and nutritional recommendations according to current guidelines

Characteristics

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

Primary Outcome

Change in HbA1c (%) within 6 months

Secondary Outcome

1) Change in HbA1c (%) within 12 months
2) Change in health literacy (European Health Literacy Survey Questionnaire (HLS-EU-Q16)) within 6 and 12 months
3) Change in daily physical activity (International Physical Activity Questionnaire (IPAQ)) within 6 and 12 months
4) Change in average steps per day (7-day average of steps/day measured by pedometers) within 6 and 12 months
5) Change in eating behavior (Fragebogen zum Essverhalten (FEV); German questionnaire on eating behavior) within 6 and 12 months
6) Change in quality of life (Short form health survey (SF-36)) within 6 and 12 months
7) Change in medical care expenses (routine data of health insurance) within 6 and 12 months

8) Change in weight (kg) within 6 and 12 months
9) Change in waist circumference (cm) within 6 and 12 months
10) Change in LDL-cholesterol concentrations (mg/dL) within 6 and 12 months
11) Change in HDL-cholesterol concentrations (mg/dL) within 6 and 12 months
12) Change in triglyceride concentrations (mg/dL) within 6 and 12 months
13) Change in systolic blood pressure (mmHG) within 6 and 12 months
14) Change in diastolic blood pressure (mmHG) within 6 and 12 months
15) Number of the combined endpoint “4P-MACE” (cardiovascular deaths, non-fatal stroke, non-fatal myocardial infarction, hospitalization due to angina pectoris) within 6 and 12 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité – Universitätsmedizin Berlin, Berlin**
- University Medical Center **Rheinisch-Westfälische Technische Hochschule Aachen, Aachen**
- University Medical Center **Universitäts-Herzzentrum Freiburg – Bad Krozingen, Freiburg**
- University Medical Center **Herzzentrum Dresden, Dresden**
- University Medical Center **Zentrum für Innere Medizin, Magdeburg**
- Doctor's Practice **Villingen-Schwenningen**
- University Medical Center **Universitätsmedizin Greifswald, Greifswald**
- Doctor's Practice **Kassel**
- University Medical Center **Klinikum rechts der Isar der Technischen Universität München, München**
- University Medical Center **Klinik und Poliklinik für Kardiologie, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/02/12**
- Target Sample Size: **1500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Gender: **Both, male and female**

- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Insured at participating health insurance,
Chronic ischemic heart disease (ICD-10: I25),
Diabetes mellitus type II (ICD-10: E11),
Permission to do sports by the study investigator,
Written informed consent

Exclusion criteria

Mental and behavioral disorders (ICD-10: F0-F99),
Heart failure NYHA IV (ICD-10: I50.14),
Malignant neoplasm (ICD-10: C25, C34, C56, C72, C73, C78, C79, C97),
Parkinson's disease (ICD-10: G20),
Alzheimer's disease (ICD-10: G30),
infantile cerebral palsy (ICD-10: G80),
chronic kidney disease (ICD-10: N18),
Trisomy 21 (ICD-10: Q90),
Blindness / visual impairment (ICD-10: H54.0, H54.2, H54.3),
Hearing loss (ICD-10: H90.0, H90.3, H90.5, H90.6, H90.8),
Care level 1-5,
Assured in a foreign country,
Inability to exercise or conditions that may interfere with exercise intervention,
No optimal medical treatment within the last 4 weeks,
Not clinically stable within the last 4 weeks,
Participation in another clinical trial

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum_LeIKD_08.05.2018**

** 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.*