# Trial Description

## Title

**Impact of a Smartphone application (KAIA COPD-App) in combination with Activity Monitoring as maintenance program following pulmonary rehabilitation in COPD : an international multi-centered randomised controlled trial**

## Trial Acronym

**KAIA COPD-001**

## URL of the trial

**[---]***

## Brief Summary in Lay Language

**The purpose of this study is to investigate how the use of a smartphone application (COPD-APP) in combination with activity monitoring in patients with chronic obstructive pulmonary disease (COPD) affects physical activity, quality of life, physical fitness, symptoms, feeling and health. For this, we compare people who carry out the program at home for half a year (training group) with persons who perform only an activity monitoring and regular tests (control group).**

## Brief Summary in Scientific Language

**The overall objective is to assess the effectiveness of the newly developed COPD-App as a maintenance program after Pulmonary Rehabilitation.**
**The primary objective is to assess the clinical efficacy of the COPD-App maintenance program on physical activity measured in steps/d in patients with COPD after 6 months.**
**Secondary objectives are to evaluate the effects of the COPD-App-program on**
- **Functional exercise capacity.**
- **Health-related quality of life (HRQoL).**
- **Patient reported health status.**
- **Exacerbations and depression and anxiety symptoms.**

**Other Objectives : Further we aim to explore the patients' compliance/adherence and safety, identify factors which facilitate the implementation of the program in the patient's home setting and to evaluate factors of the program which are especially supportive for the patients.**

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

**[---]***

## Description IPD sharing plan

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00017275**
- Date of Registration in DRKS: **2019/06/27**
- 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.: **2019-00766 , Kantonale Ethikkomission Zürich**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **J44 - Other chronic obstructive pulmonary disease**

## Interventions/Observational Groups

- Arm 1: **Device : KAIA COPD-App (Mobile Application).**
  **The study intervention is an exercise training program that requires a chair and elastic bands, consisting of training elements with progressive levels of intensity, individually adaptable to the participant's exercise level. This training program is delivered to the participants with the help of KAIA COPD-App. The individualized training sessions will last approximately 15-20 minutes and will be conducted by the participants seven days per week at home during six months of the trial period.**
- Arm 2: **Training of the control-group is performed by regular recommendations during the study period.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
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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

**The primary outcome is the change in physical activity of the intervention group in comparison to the control group, measured over one week as mean steps per day comparing baseline to 6 months visit value.**

### Secondary Outcome

**Secondary outcomes assessed are :**
**• dyspnea (COPD-Assessment test (CAT))**
**• functional exercise capacity (1-minute Sit-to stand test)**
**• HRQoL (Chronic respiratory disease questionere, CRQ)**
**• health status (Feeling Thermometer)**
**• HADS (Anxiety and depression scale)**
**• Number of exacerbations (Questionnaire as defined by GOLD Guidelines)**
**• Reaching his or her individual defined goal of physical activity**
**• Sleep efficiency and sleep quality**

## Countries of recruitment

- DE **Germany**
- CH **Switzerland**

## Locations of Recruitment

- Medical Center **Pneumologie, Zürcher RehaZentren Wald, Wald, CH**
- Medical Center **Fachzentrum für Pneumologie  Schön Klinik Berchtesgadener Land , Schönau am Königssee**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/08/09**
- Target Sample Size: **104**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**• COPD Patients willing and able to sign informed consent for use of their pseudonymized clinical data within the scope of the present interventional trial**
**• COPD patients who have completed an in-hospital pulmonary rehabilitation program with an average duration of 3 weeks.**
**• Diagnosis of COPD, defined as forced expiratory volume in 1s/forced vital capacity (FEV1/FVC)<70% predicted, FEV1<80 % predicted after bronchodilation, with or without chronic symptoms (cough, sputum production) corresponding to a GOLD stage II-IV**
**• Completion of an inpatient pulmonary rehabilitation**
**• Completion of the screening period and fulfilling of the randomization criteria as defined by the protocol**
**• Ability to use a smartphone and smartphone-apps**
**• Willingness to wear an activity tracker during study period of 6 months**
**• Male and female patients between (Minimum age) and ≥40 years of age, Females of child bearing potential must have a negative pregnancy test prior to entry in the study**
**• Knowledge of German language to understand study material, assessments and contents of the COPD-App**

### Exclusion criteria

**• The Patient is not able to conduct the exercise training program due to physical, cognitive or safety reasons, as judged by investigator; e.g., lower limb joint surgery within preceding 3 months, unstable cardiac disease, predominant neurological limitations, planned surgical or other interventions disturbing the study intervention.**
**• Significant psychiatric disorders, legal incapacity or limited legal capacity.**
**• Patients participation in another clinical trial with an investigational medication within 30 days prior to study entry.**
**• Patients already using the KAIA COPD App**

## Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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

## Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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**Germany**

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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.*