

# Telehealthcare in the Southeast of Sweden – a study on cost-effectiveness

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 02/11/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/04/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Telehealthcare (THC), in addition to standard healthcare, is cost-effective when applied to patients with heart failure. Studies performed on patients with chronic obstructive pulmonary disease (COPD; in Sweden abbreviated KOL) are contradictory. The aim of this study is to analyse the cost-effectiveness of the THC intervention.

### Who can participate?

Residents in the County Councils of Östergötland, Kronoberg and Jönköping with COPD

### What does the study involve?

Patients suitable for telehealth care are randomly allocated to either telehealth care (as a supplement to standard health care) or not (control) and followed for at least 1 year (maximum 2 years). Annual healthcare contacts and associated costs will be analysed two ways: (i) in a historical view, comparing the individual annual contacts and costs during the THC intervention with previous years without THC, and (ii) by using healthcare contacts and costs of a group of matched control patients without THC. The superiority of THC (or not) will be assessed by analysing exacerbation frequency, survival, symptom control, and quality of life before and after the intervention and compared to a group of matched control patients. The study also aims to assess the suitability of THC. Patient attitudes towards technology and patient adherence will be analysed using questionnaires and interviews, which will cover user-friendliness and patient satisfaction. Finally, collected data from symptom assessment will be explored using machine learning to find out the importance of the individual questions to predict an exacerbation.

### What are the possible benefits and risks of participating?

Possible benefits are reduced costs for health care and prevention of exacerbations, the latter leading to better control of COPD symptoms and improved quality of life. Possible risks are some patients find the interviews tiresome.

### Where is the study run from?

The County Councils of Östergötland, Kronoberg and Jönköping (Sweden)

When is the study starting and how long is it expected to run for?  
January 2020 to January 2029

Who is funding the study?  
Medical Research Council of Southeast Sweden (FORSS) (Sweden)

Who is the main contact?  
Prof. Lennart Persson, Lennart.persson@liu.se

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Lennart Persson

### ORCID ID

<https://orcid.org/0000-0002-5700-7284>

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

20220805

## Study information

### Scientific Title

The eKOL study: a randomised multi-centre study on telehealthcare of patients with chronic obstructive pulmonary disease in Southeast Sweden – a study on cost-effectiveness

### Acronym

eKOL

## **Study objectives**

It is hypothesised that telehealthcare (THC) can successfully be added to standard healthcare without any extra expense, thus, maintaining the total healthcare cost at the level expected from previous years and compared to a matched control group. It is also hypothesised that THC proves to be superior to standard healthcare regarding the effects on exacerbations, symptom control, quality of life (QoL) and survival during the study period.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 22/10/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Stockholm avdelning 2 medicin, Box 2110, SE-750 02 Uppsala, Sweden; +46 (0)10 475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: Dnr 2020-04917

## **Study design**

Multicenter interventional randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Prevention of exacerbations of chronic obstructive pulmonary disease (COPD) leading to hospitalisation

## **Interventions**

Patients suitable for telehealth care are randomised to either telehealth care (as a supplement to standard health care) or not (control) and followed for at least 1 year (maximum 2 years). Depending on their residence and local availability of telehealth care, study patients are randomised to either group.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

ImagineCare

## **Primary outcome(s)**

Annual healthcare contacts and associated costs, assessed using data from journals and data from health care registers at 24 months (in some cases also at 48 months)

## **Key secondary outcome(s)**

1. Annual exacerbation frequency assessed using data from journals at 24 months (in some cases at 48 months)

2. Annual survival assessed using data from journals and data from registers at 24 months (in some cases at 48 months)
3. Burden of COPD symptoms and quality of life assessed using the COPD Assessment Test (CAT) monthly during the study period (1-2 years)

**Completion date**

01/01/2029

## Eligibility

**Key inclusion criteria**

1. A patient offered telehealthcare service for COPD
2. Written consent to participate in the study
3. A diagnosis of COPD
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD) groups B, C or D, which in turn are decided by the COPD Assessment Test (CAT) score and exacerbation history at baseline according to the GOLD guidelines

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Unable to communicate because of hearing loss or difficulties understanding Swedish
2. Dementia or other cognitive disabilities and/or psychiatric disease of significance as judged by the study physician
3. Ongoing abuse of drugs (not tobacco) or alcohol
4. Other significant disease that dominates the clinical picture more than COPD as judged by the study physicians

**Date of first enrolment**

22/10/2020

**Date of final enrolment**

01/01/2027

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**  
**University Hospital**  
Dep. of Pulmonary Medicine  
Linköping  
Sweden  
SE-581 85

**Study participating centre**  
**Ryhov Hospital**  
Dep. of Medicine  
Jönköping  
Sweden  
SE-551 85

**Study participating centre**  
**Allmän medicinskt kunskapscentrum (AMK)**  
Region Kronoberg  
Växjö  
Sweden  
SE-351 88

## **Sponsor information**

**Organisation**  
County Council of Östergötland

## **Funder(s)**

**Funder type**  
Research council

**Funder Name**  
Forskningsrådet i Sydöstra Sverige

**Alternative Name(s)**  
Medical Research Council of Southeast Sweden, FORSS

**Funding Body Type**  
Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Lennart Persson (Lennart.persson@liu.se). Anonymised data (Excel files) can be requested from 01/01/2030 at the earliest and for a period of 1 year.

**IPD sharing plan summary**

Available on request