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

Submission date
25/09/2022

Recruitment status
Recruiting

Registration date
02/11/2022

Overall study status
Ongoing

Last Edited
13/04/2023

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Dep. of Pulmonary Medicine
University Hospital
Linköping
Sweden
SE-581 85
+46 (0)704968413
lennart.persson@liu.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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), ref: Dnr 2020-04917

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format

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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/01/2020

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

Age group
Senior

Sex
Both

Target number of participants
Two clusters, 100 participants per cluster

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

Sponsor details
Regionhuset. S:t Larsgatan 49 B
Linköping
Sweden

SE-581 91
+46 (0)10103 22 88
ekonomi@regionostergotland.se

Sponsor type
Government

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2030

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