CovidTHERAPY@HOME. Action research on development of a regionally supported, safe, feasible and scalable intervention to monitor and optimally treat patients with acute respiratory infection (including COVID-19) with or without hypoxemia and/or increased respiratory labor in their home setting

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To determine whether it is feasible in practice to optimally monitor and treat patients with COVID-19 (Utrecht: CA-ARTI) in the home setting by using an intervention that is widely supported in the region.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52259

Source
ToetsingOnline

Brief title
CovidTHERAPY@HOME

Condition

- Other condition
- Respiratory tract infections

Synonym
COVID-19; SARS-CoV-2 infection, RTI; pneumonia; influenza

Health condition

COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Zilveren Kruis;ZonMw

Intervention

Keyword: COVID-19, home treatment, hospital at home, influenza, pneumonia, respiratory tract infection, RTI, substitution of care

Outcome measures

Primary outcome

Feasibility defined as reaching a stable, regionally supported intervention to

optimally treat patients with (strong suspicion of) COVID-19 (Utrecht:

CA-ARTI)and hypoxemia and/or increased respiratory effort in their home setting

by evaluation in short cycles assessing the care trajectory of 45 patients

within the study

Secondary outcome

- Feeling of safety during the first two weeks of illness as reported by the

patient

- Disability-free survival after 30 days (% change in WHODAS-2 questionnaire

between baseline and day 30)

- Number of days living at home during 30 days follow-up

- Time to discharge from medical follow-up (defined as last contact with

healthcare professional based on EHR)

- Number of GP contacts during 30 days follow-up

- Number of emergency room visits during 30 days follow-up

- Proportion of patients admitted to hospital at 30 days follow-up

- Characteristics of hospitalization within 30 days follow-up

- Mortality at 30 days follow-up

- Cost-benefit analysis

Study description

Background summary

The CovidTherapy @ Home project focuses on the development and evaluation of a regionally supported, safe, feasible and scalable intervention (both medical and organisational) to optimally monitor and treat patients presenting to primary care with COVID-19 (Utrecht: CA-ARTI)

Study objective

To determine whether it is feasible in practice to optimally monitor and treat patients with COVID-19 (Utrecht: CA-ARTI) in the home setting by using an intervention that is widely supported in the region.

Study design

Action research in which the intervention will be further developed through short-cycle evaluation rounds by the research team together with an expert panel by analysing the data collected so far. The initial intervention has been designed on scientific literature review, practical experience and expert input. This monocenter, observational pilot study concerns the phase of the action research in which we will prospectively collect data from 45 patients in the region to further shape the intervention. A parallel process evaluation will be performed by conducting semi-structured interviews with patients and caregivers and relevant health care professionals.

Intervention

A region-wide protocol-based intervention to optimally monitor and treat

patients with (a strong suspicion of) COVID-19 (Utrecht: CA-ARTI) at home. The intervention consists of intensive home monitoring of vital signs and, depending on the severity of the disease, addition of treatment with oxygen via nasal cannula, oral corticosteroids, antibiotics and thrombosis prophylaxis.

Study burden and risks

The intervention encompasses a risk for the first group of patients (category 1) since those patients are not treated in the more controlled setting of the hospital but in the home setting. To reduce this risk, several prerequisites and safety nets have been created and described. For category 0 and 2 no a risks are associated with participation. However, the extra burden consists of keeping track of and reporting thevital signs **for monitoring purposes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Three categories of patients will be included:

Category 0:
Patients with moderate to severe COVID-19 (Utrecht: acute respiratory tract infections) and co-morbidity, without hypoxemia and/or respiratory distress, who would normally stay at home without structural monitoring by a regional monitoring entity.

Category 1:
Patients with COVID-19 (Utrecht: acute respiratory tract infections) and hypoxemia and/or respiratory distress without signs of clinical instability who normally would be admitted to a hospital COVID ward for treatment

Category 2:
Patients with (a strong suspicion of) COVID-19 (Utrecht: acute respiratory tract infections) and hypoxemia and/or respiratory distress for whom hospitalisation is not considered desirable, but treatment at home is considered desirable.

Inclusion criteria for category 0:
- Nijmegen Positive SARS-CoV-2 test (PCR or rapid antigen test) with moderate-severe complaints (>=three days: temperature >=37.5*C; and/or new complaints of cough, nose cold, sore throat combined with shortness of breath or combined with fatigue)
- Utrecht: clinical diagnosis of community-acquired acute respiratory tract infection (CA-ARTI):
-- at least two respiratory symptoms: cough, sore throat, runny nose, nasal congestion, dyspnea AND
-- at least one systemic symptoms: fever, feverish, chills, fatigue, headache, myalgia, loss of smell, loss of taste AND
-- clinician judges that symptoms are most likely attributable to CA-ARTI.
- No indication for hospital referral: no hypoximia (measured at rest; SpO2 >94%); no increased respiratory effort (measured at rest; respiratory rate <24/min); haemodynamically stable (blood pressure > 120/80 mmHg and heart rate >50/min and <100/min)
- Sufficient proficiency of the Dutch language to provide informed consent (or translator available to mitigate the language barrier)
- Patient is at risk for complicated disease course (age >70, and/or immunocompromised, and/or chronic kidney disease, and/or cardiovascular disease, and/or diabetes mellitus, and/or COPD, and or liver cirrhosis, and/or obesity (BMI>40)).

Inclusion criteria for category 1:
- Nijmegen Positive SARS-CoV-2 test (PCR or rapid antigen test)

- Utrecht: clinical diagnosis of community-acquired acute respiratory tract infection (CA-ARTI):
-- at least two respiratory symptoms: cough, sore throat, runny nose, nasal congestion, dyspnea AND
-- at least one systemic symptoms: fever, feverish, chills, fatigue, headache, myalgia, loss of smell, loss of taste AND
-- clinician judges that symptoms are most likely attributable to CA-ARTI.
- GP considers referral to hospital because of hypoxemia (SpO2 <94% at rest, and/or increased respiratory effort with respiratory rate >24/min at rest)
- Haemodynamically stable (blood pressure > 120/80 mmHg and heart rate >50/min and <100/min)
- Partner/caregiver present at the patient's home for providing supportive care
- Capable of using a pulseoximeter (or caregiver can help)
- Age 18 years or older
- Mentally competent
- Sufficient proficiency of the Dutch language to provide informed consent (or translator available to mitigate the language barrier)

Inclusion criteria for category 2 :
- Nijmegen Strong suspicion of COVID-19 or positive SARS-CoV-2 test (PCR or rapid antigen test)
- Utrecht: clinical diagnosis of community-acquired acute respiratory tract infection (CA-ARTI):
-- at least two respiratory symptoms: cough, sore throat, runny nose, nasal congestion, dyspnea AND
-- at least one systemic symptoms: fever, feverish, chills, fatigue, headache, myalgia, loss of smell, loss of taste AND
-- clinician judges that symptoms are most likely attributable to CA-ARTI.
- Hospitalisation is not considered desirable, but treatment at home is considered desirable.
- Hypoxemia (SpO2 <94% at rest, and/or increased respiratory effort with respiratory rate >24/min at rest)
- Partner/caregiver present at the patient's home for providing supportive care
- Capable of using a pulseoximeter (or caregiver can help)
- Age 18 years or older
- Mentally competent
- Sufficient proficiency of the Dutch language to provide informed consent (or translator available to mitigate the language barrier)

Exclusion criteria

Exclusion criteria for all three patients categories:
- Active smoking (due to associated risks with oxygen therapy)
- Severe dementia or severe psychiatric illness (patient is not able to follow studyinstructions)

- Inadequate mastery of the Dutch language and absence of care giver who can translate to mitigate the language barriaer.

Additional exclusion criteria for category 1:
- Severe clinical condition warranting intensive treatment in hospital setting or ICU admission
- More medical care is necessary than can be organised in the home setting
- Chronic pulmonary disease, heart failure, immunocompromised status, kidney failure or liver failure of which decompensation risk is deemed too high by treating physician and necessitates clinical admission
- PE/DVT in past month

Additional exclusion cirteria for category 2:
- severe disease or such critical clinical condition that the physician decides to abstain all care

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-11-2021
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	14-05-2021
Application type:	First submission
Review commission:	METC NedMec

Approved WMO Date:	26-01-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-07-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-12-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22655
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL77421.041.21
Other	NTR: NL9459
OMON	NL-OMON22655