Early@home

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28634

Source
Nationaal Trial Register

Brief title
Early@home

Health condition

COVID-19

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Days alive at home 30 days after randomization

Secondary outcome

- Mortality, in hospital and 30 days after randomization
- COVID-19 specific mortality, in hospital and 30 days after randomization
- Total hospital length of stay

- Number of ED visits or unplanned outpatient clinic visits 30 days after randomization
- Number of general practitioner visits 30 days after randomization
- Number of hospital readmissions
- Number of intensive care unit readmissions
- Score for physchological wellbeing at start and discharge

Study description

Background summary

Rationale: The large number of hospital admissions for COVID-19 puts a significant strain on patients and hospital organizations alike. Patients experience more depression and anxiety due to hospital admission in contact isolation. Hospital organizations have to ensure enough available hospital beds for those in need, which has proven to be challenging during surges of SARS-CoV-2 infections. Relocating hospital care to the home situation, assisted by telemedicine, might improve the number of days at home for patients recovering of COVID-19 without compromising patient safety.
Objective: The primary objective is to assess the safety and efficacy of the “Early@home” telemedicine system that relocates hospital care for COVID-19 patients to the home situation. The secondary objective is to assess the impact of this intervention on the psychological wellbeing of patients.
Study design: Early@home is an open, randomized, controlled trial. Patients will be randomized 1:1 to either the intervention group or the group receiving care as usual.
Study population: The study population will consist of patients who are admitted to the hospital with COVID-19, who are in the recovering phase of disease and who are expected to be discharged home.
Intervention: The intervention will consist of relocated hospital care, possibly with oxygen therapy at home. Patients will fill out a questionnaire three times a day using a mobile telephone application designed for telemonitoring. The questionnaire consists of three symptoms, temperature and oxygen saturation. A monitor team, under supervision of a medical specialist, will contact each patient daily to discuss the measurements and adapt treatment if necessary.
Main study parameters/endpoints: The primary endpoint is the difference in number of days alive at home, 30 days from randomization. Secondary endpoints are the difference in mortality, hospital length of stay, readmission to the hospital and to the ICU, number of unplanned visits to the hospital and number of visits to the general practitioner, and Hospital Anxiety and Depression Scale score after randomization and at discharge.

Study objective

Relocated hospital care with telemedicine will improve the number of days alive at home for patients with COVID-19

Study design

T0= randomization, T30= 30 days after randomization. All other timepoints depend on the situation.

Intervention

Relocated hospital care with telemedicine

Contacts

Public
UMC Utrecht
Harriët van Goor

0887567967
Scientific
UMC Utrecht
Harriët van Goor

0887567967

Eligibility criteria

Inclusion criteria

- The patient is in the recovery phase of COVID-19 and receives low flow oxygen therapy or no oxygen therapy
- The patient is 18 years of age or older;
- The patient is admitted to the hospital with COVID-19 pneumonia;
- The patient is expected to be discharged home;
- A partner/primary caregiver is available at the patients home for support;
- A rectal thermometer is available;
- The patient is in possession of a smartphone with the ability to host the Luscii app;
- The patient or the caregiver is able to use the smartphone and Luscii app;
- The patient or the caregiver is able to use the pulse oximeter;
- The patient or the caregiver is able to speak, read and understand the Dutch language sufficiently enough to be able to use the Luscii app;

Exclusion criteria

- A patient with dementia or severe psychiatric disorder who is unlikely to be compliant to the

intervention (to be determined by treating physician);
- A patient who is discharged to a care facility or rehabilitation center;
- A patient who needs more medical support than can be organized at home.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2021
Enrollment:	62
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9081
Other	METC UMCU : 20-783

Study results