REal-time data monitoring for Shared Adaptive, Multi-domain and Personalised prediction and decision making for Long-term pulmonary care Ecosystems (RE-SAMPLE) Prospective Study Virtual Companionship Programme

Published: 31-10-2024
Last updated: 22-12-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON57083

Source
ToetsingOnline

Brief title
RE-SAMPLE VCP

Condition

- Heart failures
- Glucose metabolism disorders (incl diabetes mellitus)
- Respiratory tract infections

Synonym
Chronic Obstructive Pulmonary Disease (COPD) with comordities

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Europese Unie (Horizon2020)

Intervention

Keyword: Chronic comorbidity, COPD, Exacerbations, Virtual Companionship Programme

Outcome measures

Primary outcome

The primary study outcome is the feasibility of the VCP measured through an evaluation of clinical outcomes (e.g. duration of exacerbations assessed by daily symptom diaries), user acceptance, usability and patient engagement.

Secondary outcome

Acceptance of the VCP will be measured by collecting feedback with questionnaires and in-depth interviews with patients and HCPs at the end of the follow up period.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a common progressive lung condition with distressing exacerbations. Many patients with COPD have multiple complex chronic conditions (CCCs) such as cardiovascular diseases, that increase the patient burden, mortality, healthcare consumption and costs. These multi-morbidities in COPD can trigger exacerbations, increase common risk factors, and have overlapping symptoms and pathophysiology. The complexity of CCCs requires in-depth understanding of the interplay of not only individual clinical CCC characteristics, but also the patient*s capabilities, functional limitations, preferences, and behaviour. Additional critical factors typical of chronic diseases, such as fragmentation of visits, complexity of care patterns,

and impact of lifestyle call for more personalised treatments. Digital technologies can support such patient-specific approaches by introducing tools that enable self-management and more continuous patient-healthcare provider interactions, leading to so-called virtual companionship programs, where indeed disease-centred digital solutions could materially improve overall care efficacy and clinical outcomes. In addition, the integration of Real World Data (RWD) gathered through such solutions with clinical data will boost the output on predictions and patterns of exacerbations and impact disease management by generalising results from clinical research to routine clinical practice. In order to support patients with COPD and CCCs, the RE-SAMPLE consortium has developed a Virtual Companionship Programme (VCP) which will support both healthcare professionals (HCPs) and patients in managing their multimorbid disease using a tailored approach.

Study objective

The main objective of the RE-SAMPLE VCP is to facilitate proactive disease management of COPD and CCCs. The study goal is to evaluate the feasibility of the VCP by assessing improvements in clinical outcomes, user acceptance, usability, and engagement in the care pathway of patients with COPD. The virtual companion will, in fact, support patients with COPD and CCCs in their self-management behaviour and enable an effective communication approach, where HCPs and patients can leverage technologies to have timely, tailored, and targeted treatments.

Study design

This is a pragmatic descriptive study to evaluate the feasibility and user acceptance of a VCP adopted in daily life with a 9-month follow-up. The adaptive and personalised VCP consists of three parts: i) Virtual companion for the patient, ii) active support programme for the healthcare professional, and iii) monitoring and communication console in a non-hospital setting. Measurements on clinical outcomes and user adherence are collected through the Healthentia mobile phone application at baseline, daily, at exacerbations or flare-ups, during follow-up visits and from hospital data. Additionally, individual semi-structured interviews are conducted with patients and involved HCPs to obtain in-depth information regarding their perceived effectiveness of the VCP, preferences, and additional needs (including facilitators and engagement motivators) to improve its potential uptake and adherence.

Intervention

The adaptive and personalised VCP consists of three parts: i) Virtual companion for the patient (mobile application) including a self-management intervention for COPD and CCCs, ii) active support programme for the HCP (clinical dashboard), and iii) monitoring and communication console in a non-hospital

setting (mobile application).

Patients will be stimulated in self-managing their COPD and CCC's. At baseline all patients will attend a 2-hour group session where they receive information regarding their COPD and CCC'S, such as; Diabetes, Chronic heart failure, Ischemic heart disease, Paroxysmal atrial fibrillation, and anxiety and/ or depression. They will be informed about the disease, management of the disease, recognition of symptoms, common medication for the disease and how the disease can impact one*s life. Patients can also ask questions and share experiences regarding the COPD and or CCC's in the group session.

Following the group session all participants will attend a one-hour individual meeting with a casemanager (pulmonary nurse) where their individual action plan will be set-up based on their preferences and needs in personal goals (e.g. physical activity). They will also be taught what actions to take when the symptoms of their COPD and/ or CCC's increase compared to their usual symptoms (e.g., when to start self-treatment of an exacerbation or when to call a HCP for support).

Every three months the action plan will be reviewed by the HCP and patients. Goals will be adjusted where needed by a phone call-meeting. If needed the 3-month review meetings by phone can be adjusted to physical appointment if either the patient of HCP sees fit.

In addition to the group session, individual meeting and review meetings, patients will be asked to visit the hospital three more times for a spirometry, 6-minute walking test and blood test, these will be performed at baseline, month 6 and at the end of the study (month 9). If a patient already performed - one of - these tests 3 months prior to baseline and is stable, thus did not have any flare-ups or exacerbation of their COPD and CCC's, this measurement can be used for the base-line measurement and there will be one less hospital visit for the patient.

Within the VCP study some patients will use a smart-inhaler, similar to their current inhaler, that collects data on inspiratory flow, inhaled volume and inhalation duration. This data will enable the researchers retrospectively to assess whether smart-inhalers have a predictive value in the development of AECOPD.

Study burden and risks

The risk for adverse events due to participation in this study is negligible as medical treatment of the patients will be continued and they will receive regular usual care during the study.

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

For a patient to be eligible to participate in the study the following criteria:

Clinical diagnosis of COPD according to the GOLD criteria [5] (FEV1 < 80% of the predicted value and FEV1/FVC < 0.70);

Patients can be included both at stable state and during exacerbation/hospitalization;

At least one comorbidity:
-diabetes mellitus (glucocorticoid-induced, or stable type 1 or 2),
-chronic heart failure (clinical diagnosis according to the ESC guidelines

[26]),
-ischaemic heart disease (history of myocardial infarction, angina pectoris),
-active symptoms of anxiety and/or depression (>=11 Hospital Anxiety and Depression Scale [27,28], and/or anxiety or depression symptoms being treated at the time of inclusion),
-paroxysmal atrial fibrillation (clinical diagnosis according to the ESC guidelines [29]),
-obstructive sleep apnoea syndrome (OSAS) (Dutch specific guidelines, based on AASM guidelines [30,31]);

OR at least two risk factors for developing comorbidities:
-Active smokers,
-High BMI (>=30),
-Low BMI (<18.5),
-Atrial hypertension (Diastolic blood pressure >=140 mmHg and/or systolic blood pressure >=90 mmHg)
-Hypercholesterolemia (LDL-cholesterol >5.0 mmol/L or total cholesterol >8.0 mmol/L),
-Kidney failure which requires dialysis;

Under treatment at one of the pilot sites (MST, TUK, GEM);

>40 years of age;

Smoker or ex-smoker;

Able to understand, read and write the language spoken in the country of the pilot site.

Written informed consent from the subject prior to participation.

Participant must be able to use digital equipment such as smartphone/tablet/smartwatch.

For healthcare professionals to be eligible to participate in the study the following criteria must be met:
-Working at one of the pilot sites (MST, TUK, GEM)
-Using the VCP during the treatment of their patients
-Written informed consent from the subject prior to participation.

Exclusion criteria

Low chance for survival:
-Patients who started a palliative care programme,

-Patients with active malignancies for which chemotherapy and/or radio therapy is currently prescribed,
-Low survival probability, based on physician assessment;

Presence of the following other active lung disease:
-Asthma,
-Lung cancer,
-Tuberculosis,
-Interstitial lung disease with the exception of fibrosis due to COPD;

Severe psychiatric illness, diagnosed by anamnesis;

Patients with cognitive impairment (Mini Mental State Examination (MMSE) < 24) [34].

Patients with maintenance therapy of antibiotics.

Patients who requested not to be contacted for the VCP.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-11-2024
Enrollment:	53
Type:	Anticipated

Medical products/devices used

Generic name:	Healthentia
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-10-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT04955080
CCMO	NL86899.100.24