Research Protocol

Evaluating the feasibility of a mobile self-management application for patients with Chronic Obstructive Pulmonary Disease (COPD)

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Title	Evaluating the feasibility of a mobile self-management application for patients with Chronic Obstructive Pulmonary Disease (COPD)
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Subsiding party	NA
Independent expert(s)	
Laboratory sites	NA
Pharmacy	NA

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

CCMO	Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek
COPD	Chronic Obstructive Pulmonary Disease
EMR	Electronic Medical Record
IT	Information technology
WMO	Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen)

1. INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) affects over 250 million people worldwide [1], and almost 600.000 people in the Netherlands [2]. In 2020 it is expected to be the third leading cause of death [3]. COPD is "a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases" [3]. The most common symptoms are dyspnea, chronic coughing and sputum production [3, 4]. An acute worsening of the symptoms called an exacerbation [4, 5]. Exacerbations lead to additional care [3] and often to hospital admission [6], with considerable costs involved [7]. Multiple factors are associated with a higher risk for admission to the hospital for exacerbation including: previous admission, oral corticosteroids [8], dyspnea [8, 9], and increased $PaCO_2$ [10] and older age [8, 9]. Although the results for age are contradictory [8].

Self-management interventions have the potential to reduce exacerbations and improve patients' management over their health [11]. Behavior change is essential to achieve or improve self-management [12, 13]. To enhance self-management patients should gain more knowledge and skills especially about their condition, medication, smoking cessation and when to ask for help [3]. COPD self-management interventions are defined as "structured but personalized and often multi-component, with goals of motivating, engaging and supporting the patients to positively adapt their health behavior(s) and develop skills to better manage their disease" [14]. Important features of COPD self-management programs include: (1) smoking cessation, (2) recognition and treatment of exacerbation, (3) physical activity, (4) nutrition and (5) management of dyspnea. Additionally, relations with healthcare professionals, family and friends [14], breathing techniques, and stress management are important [12]. These interventions should be tailored to the specific situation of an individual patient, for which action-plans can be used [13].

The use of information technology in health care is promising [15] and can improve patients' self-management [16]. In a recent Cochrane review it is reported that self-management interventions with a COPD exacerbation action plan can lead to a lower chance of respiratory-related hospitalizations [17]. However, only four studies were supported by information technology (IT), including integrated care programs using a web-based call center for patients to contact a nurse [18, 19] and e-learning for COPD management [20]. In these studies positive effects on readmissions were found [18, 20], knowledge and treatment adherence [19]. Tabak et al. [21] used a web-portal including a physical activity program, teleconsultation and self-management. Overall, in this study the use was good and patients were satisfied [21]. Technology can also be used to support patients at home. However, the added value of these intervention is not always clear, because these interventions are often part of a larger initiative to improve care [5].

Mobile health (mHealth), the use of mobile devices for example tablets and smartphone, is often used in healthcare for example for patient education, to enable health care professionals to monitor patients' health [22] for communication and information exchange [23]. In mHealth interventions a number of features are implemented, some are more common for example questionnaires and education and others less common for example personalized feedback. More research on mobile applications is needed, especially because there is a lack of knowledge about the features provided in the for COPD patients [22].

In this study we will evaluate the feasibility of a mobile self-management application for patients with COPD who are at high risk for readmission.

2. OBJECTIVES

This study will evaluate the feasibility of a mobile self-management application for patients with COPD who are at high risk for readmission. The use (actual use according to log data) and overall satisfaction will be evaluated. Also the changes in self-management will be assessed, satisfaction about the different elements of the app andpreliminary evidence of the effects on hospital readmissions will be generated.

3. STUDY DESIGN

This is a one group, feasibility study with assessments at baseline and after the intervention.

4. STUDY POPULATION

4.1 Population (base)

We will include Dutch patients diagnosed with COPD. Patients will be recruited during their admission for an exacerbation in Rijnstate hospital in Arnhem. In total 113 patients were readmitted in the period october 2017 until march 2018. Assuming a participation rate of 40% we will be able to include 45 patients in a 6-month period.

4.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- diagnosed with COPD
- Age > 18 years
- admission to the hospital for exacerbation
- at least one hospitalization for COPD exacerbation in the year preceding this study
- having (access to) a tablet or smartphone
- working internet connection

- proficiency in using a tablet or smartphone

- ability to read and understand the Dutch language

- signed informed consent

Healthcare professionals:

- pulmonologists, nurse practitioners and (specialized) nurses treating patients with COPD

4.3   Exclusion criteria

Patients who meet one of the following criteria will be excluded from the study:

- No exacerbation of COPD

- Comorbidities: cancer, severe cognitive or psychiatric comorbidities

- no internet access

- no access to a tablet or smartphone

4.4   Sample size calculation

NA

5.   TREATMENT OF SUBJECTS

5.1   Investigational product/treatment

During their admission in the hospital patients will be informed about the application and asked to download the app. A nurse will inform and support patients. The application provides patients with a 8 week self-management program that consists of the following functionalities:

- *Lung exacerbation action plan (in Dutch: Longaanval actieplan)*
  The lung exacerbation action plan (LAP) is provided by the Lung Foundation ('Longfonds'in the Netherlands) and digitalized in the application. During admission in the hospital, patients will fill in the action plan together with a pulmonary nurse. The LAP helps patients to recognize change in their symptoms and guide them how to act upon these changes. The action plan consists of different categories and colors: 'I am doing well today' (green), 'I feel worse' (yellow), "No improvement after 2 days" (orange) and 'The situation is threatening' (red). All levels include advices about their symptoms (for example dyspnea, production of sputum, coughing), medication, physical activity and nutrition. It is also possible to request a consult with a nurse after using the LAP. Patients can access and use the LAP at any time using the mobile application.

- *Questionnaires*

  In order to monitor patients' health condition, we will ask them to fill in questionnaires during the 8 weeks. The following questionnaires are included in the self-management program: the Clinical COPD Questionnaire (CCQ) (weekly), the Hospital Anxiety and Depression Scale (HADS) (in week 1 and week 8) and weight (during admission and in week 8). The total score of the CCQ will also be accessible in the app.

- *Information and education*

  During the 8 weeks, patients will receive daily information about COPD, exacerbations, medication, nutrition, physical activity and smoking (if relevant). Every week patients also receive a question to test their knowledge about the given information.

- *Video consultation*

  Video consults will be planned in week 4 and week 8, with a pulmonary nurse. Patients can request a video consult. The pulmonary nurse will contact the patient between 13.00-13.30pm with a video consult, the same day or the next day.

5.2 Use of co-intervention (if applicable)

NA

5.3 Escape medication (if applicable)

NA

6. INVESTIGATIONAL PRODUCT

NA

7. NON-INVESTIGATIONAL PRODUCT

NA

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter

The main study parameter is feasibility and will be evaluated by the components use and satisfaction. Feasibility will be determined considering outcomes of these outcomes and minimum levels for a successful program are provided below.

8.1.1.1 Expectations and experience – according to constructs of the UTAUT model

Questionnaire that consist of questions covering constructs of the Unified Theory of Acceptance and Use of Technology (UTAUT) [24] model will be used to measure expectations and experiences of use of mobile application. The UTAUT consists of four constructs that influence behavioral intention and behavior: (1) performance expectancy, (2) effort expectancy, (3) social influence, (4) facilitating conditions. The items will be rated on a seven point scale. Results will be presented as mean and standard deviation (SD). Use (experience) is measured on a 7-point Likert scale.

8.1.1.2 Actual use (log data)

Use will be monitored with log data of the application. To evaluate feasibility we will also look at the log data for frequency and time of use of the total number of patients.

8.1.1.3 Satisfaction

All patients will be asked to complete questions about satisfaction with the self-management application, the information in the app and the user-friendliness of the app. This will be measured with a five-point likert scale. We will also ask patients about their overall satisfaction (on a scale of 1 – 10).

8.1.2   Secondary study parameters/endpoints (if applicable)

8.1.2.1 Self-management

The Partners in Health scale (PIH) will be used to measure self-management [25]. The PIH is a 12-item scale and indicated good psychometric properties with reported internal consistency (Cronbach's alpha = 0.82). In this study the Dutch version of the PIH will be used consisting of 12-items and of two subscales: (1) knowledge and coping; (2) recognition and management of symptoms, adherence to treatment. The correlation between the two subscales is 0.43 [26]. The items will be rated on a 9-point Likert scale (0 – high self-management and 8 low self-management).

8.1.2.2 Hospital readmissions

A hospital readmissions (a readmission in the hospital for as least of 24 hours). The number of, including the reason for, hospital admissions will be monitored and this information will be obtained from the Electronic Medical Record (EMR).

8.1.2.2 Emergency room visits

The number of, including the reason for, emergency room visits per patient will be monitored and this information will be obtained from the Electronic Medical Record.

8.1.2.3 Satisfaction healthcare professionals

After the last patient finishes the self-management program, health care professionals will also be asked to fill in a questionnaire to measure effects on:

- Experiences the application
- Experiences with monitoring the questionnaires
- Satisfaction
- Organizational advantages/disadvantages for example time investment, efficiency of work processes.

8.1.3 Other study parameters (if applicable)

The patients' age, marital status, education, experience with internet and internet use, tablet/smartphone skills and support (with tablet/smartphone use) will be measured using questionnaires. The GOLD stage, comorbidities, number of admissions and emergency room visits for exacerbations, reason for admission and emergency room visits we will extract from the EMR. We will obtain the results from the CCQ and HADS from the mobile COPD application.

8.2 Randomisation, blinding and treatment allocation

NA

8.3 Study procedures

This study consists of two stages: 1) usability testing and 2) feasibility study.

8.3.1 Usability testing

Before the start of the feasibility study we will use usability testing techniques to receive feedback on a prototype of the application. We will use the 'thinking aloud method' for this usability testing. We will ask approximately 5-10 patients (until saturation is achieved) that are admitted in the hospital for a COPD exacerbation about their opinion regarding the app. Specifically we will give them some assignments for example "can you find the lung action plan and use it", "can you fill in the CCQ", "can you find and read the information about nutrition". We will also ask patients about their opinion about the information, the length of the text, the readability, the frequency of new information in the app (daily), the knowledge questions. Based on this information we will adjust the application. Results from the usability testing will be used to improve the app.

8.4.2 Feasibility study

Patients are informed by the study during a readmission (for exacerbation) in the hospital by a pulmonary nurse and they will also receive the patients information. One day (24 hours) before their discharge patients are asked for informed consent. The pulmonary nurse is also available to answer patients questions. The researcher (Laura Kooij) is available for the nurses to answer their questions. After signing the informed consent patients will be asked to fill in the baseline questionnaire and they are provided with information on how to download the app. If necessary, the nurse is available for support. The nurse and the patient will also fill in the lung exacerbation action plan and the nurse will tailored the app (according to the lung exacerbation action plan and smoking yes/no). The self-management program consists of the lung exacerbation action plan, questionnaires, information and education, and contact (using video consult). Patients will be asked to fill in a questionnaire for study purposes at:

- Baseline

  The questionnaire at baseline covers the aspects of self-management, expectations and socio-demographics.

- T1 - after 8 weeks, after finishing the self-management program

  The questionnaire at T1 covers aspects of self-management, experiences, use and satisfaction with the application and the received information.

- T2 - after 5 months (3 months after finishing the self-management program)

  The questionnaire at T=2 covers aspects about self-management, experiences, satisfaction and use.

8.4   Withdrawal of individual subjects

Patients can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a patient from the study for any medical reasons.

8.4.1   Specific criteria for withdrawal (if applicable)

NA

8.5   Replacement of individual subjects after withdrawal

Subjects will not be replaced after withdrawal.

8.6   Follow-up of subjects withdrawn from treatment

NA

8.7   Premature termination of the study

NA

9. SAFETY REPORTING

It is not expected that this study will jeopardize subject health or safety or will result in adverse effects.

10. STATISTICAL ANALYSIS

10.1 Primary study parameter(s)

The main study parameter is feasibility and this will be evaluated in terms of use and satisfaction. We will use descriptives statistics to report on use (according to the log data) and satisfaction (mean and SD).

10.2 Secondary study parameter(s)

10.2.1 Self-management

Changes in the parameter 'self-management' as measured with the PIH questionnaire will be assessed from baseline to 8 weeks and to 5 months and will be analyzed using a mixed model.

10.2.2 Number of readmission

The number of readmission, the clinical (>24 hours) and day admissions (<24 hours), emergency room visits and the reasons for the admission(s) and the visit(s) will be obtained from the EMR after 30 days, 8 weeks, 5 months, 12 months and 24 months. The percentages of readmissions and emergency room visits will be compared with the numbers of the year preceding the study (from the hospital registry) by using descriptie statistics.

10.3 Other study parameters

Descriptive statistics (frequencies, percentages, means, standard deviations etc.) will be used to present sociodemographic and clinical variables as well as internet skills, tablet/smartphone skills.

10.4 Interim analysis (if applicable)

NA

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

The handling of personal data will be in accordance with the Dutch Personal Data Protection Act (in Dutch: Algemene verordening gegevensbescherming (AVG)).

11.2 Recruitment and consent

During hospitalization patients will be informed about the study by a pulmonary nurse. And they will be provided with the patient information regarding this study. Patients 2 to 3 days to think about participation in the study. During their last consult before discharge, 24 hours before discharge, patients are asked to sign informed consent. After that they will be informed about the application and get support downloading the application.

11.3 Objection by minors or incapacitated subjects (if applicable)

NA

11.4 Benefits and risks assessment, group relatedness

NA

11.5 Compensation for injury

NA

11.6 Incentives (if applicable)

NA

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

Data will be handled confidentially. A subject identification score list will be used to link the data to the subject. The key code will be safeguarded by the investigator (Laura Kooij) and will be saved on a computer in the work office at Rijnstate hospital. The data will be coded using numbers in order enrolment, 1 / 2 / 3 etc. The investigators Laura Kooij and the pulmonologists P.J.E. Vos, MD, PhD and A. Dijkstra, MD will have access to the source data. Data will be stored for at least 15 years in an office at Rijnstate hospital.

12.2 Monitoring and Quality Assurance

NA

12.3 Amendments

NA

12.4 Annual progress report

NA

12.5 End of study report

The investigator will submit a final study report with the results of the study including any publications/abstracts of the study, to the Board of Directors and the Local Feasibility Committee of the hospital.

12.6 Public disclosure and publication policy

The investigators will publish the results of the study as soon as appropriate.

13. STRUCTURED RISK ANALYSIS

We used the risk analysis provided by Rijnstate. The use of this checklist resulted in the classification of the risk of this study as 'little'. Because the estimated change for damage is 'little', the level of severity of the damage is 'light' and there is no vulnerable population included in the study.

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