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ORIGINAL RESEARCH

Effects of Adherence to an mHealth Tool for Self-Management of COPD Exacerbations

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Purpose: Poor adherence to COPD mobile health (mHealth) has been reported, but its association with exacerbation-related outcomes is unknown. We explored the effects of mHealth adherence on exacerbation-free weeks and self-management behavior. We also explored differences in self-efficacy and stages of grief between adherent and non-adherent COPD patients.

Patients and Methods: We conducted secondary analyses using data from a recent randomized controlled trial (RCT) that compared the effects of mHealth (intervention) with a paper action plan (comparator) for COPD exacerbation self-management. We used data from the intervention group only to assess differences in exacerbation-free weeks (primary outcome) between patients who were adherent and non-adherent to the mHealth tool. We also assessed differences in the type and timing of self-management actions and scores on self-efficacy and stages of grief (secondary outcomes). We used generalized negative binomial regression analyses with correction for follow-up length to analyze exacerbation-free weeks and multilevel logistic regression analyses with correction for clustering for secondary outcomes.

Results: We included data of 38 patients of whom 13 (34.2%) (mean (SD) age 69.2 (11.2) years) were adherent and 25 (65.8%) (mean (SD) age 68.7 (7.8) years) were non-adherent. Adherent patients did not differ from non-adherent patients in exacerbation-free weeks (mean (SD) 31.5 (14.5) versus 33.5 (10.2); p=0.63). Although statistically not significant, adherent patients increased their bronchodilator use more often and more timely, contacted a healthcare professional and/or initiated prednisolone and/or antibiotics more often, and showed at baseline higher scores of self-efficacy and disease acceptance and lower scores of denial, resistance, and sorrow, compared with non-adherent patients.

Conclusion: Adherence to mHealth may be positively associated with COPD exacerbation self-management behavior, self-efficacy and disease acceptance, but its association with exacerbation-free weeks remains unclear. Our results should be interpreted with caution by this pilot study's explorative nature and small sample size.

Keywords: COPD, mHealth, adherence, exacerbations, self-management, self-efficacy, grief

Introduction

An exacerbation of chronic obstructive pulmonary disease (COPD) is characterized by increased dyspnea and/or cough and sputum that worsens in <14 days. Symptoms may be accompanied by tachypnea and/or tachycardia and are often associated with increased local and systemic inflammation caused by infection, pollution, or other insult to the airways.[1] Exacerbations are common in patients with COPD and up to 60% of the patients experience ≥2 exacerbations per year.[2] Exacerbations have a negative impact on patient's health status and may result in hospitalization.[3,4] Even though the impact of exacerbations can be significant, patients often have trouble recognizing symptom worsening and adjusting treatment.[5,6] To improve recognition and self-management of exacerbations, patients may use a paper action plan, ie a guide including strategies to apply when symptoms worsen.[7,8] However, not all patients apply self-management strategies consistently.[9]

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Telehealth, an umbrella term for health-related services via digital communication technologies, seems promising in supporting COPD patients and improving their self-management behavior.[10,11] Mobile health technologies (mHealth), a form of telehealth, may support patients in monitoring their physiological status, such as blood oxygen level, pulse rate, activity level, or health behavior.[12] However, most mHealth applications lack personalized feedback which is needed to adopt mHealth into healthcare.[13] We have previously developed an mHealth application to promote self-management of COPD exacerbations. The mHealth application predicts exacerbation risk and provides personalized treatment advice without remote monitoring by healthcare professionals.[14] Treatment advice depends on the patient's entries in the application and a built-in Bayesian network decision model. The sensitivity and specificity of the application appeared to be high.[15] We studied the effects of the mHealth tool in a randomized controlled trial (RCT), but it did not differ statistically significant from a paper action plan on exacerbation-related outcomes.[16]

Whether this could be explained by low adherence rates, thereby decreasing the potential effect of the mHealth tool on self-management behavior and exacerbation-related outcomes, has not yet been explored. Low adherence rates in COPD telehealth studies have been described before.[17] However, there is a lack of knowledge on the relation between patients' adherence to mHealth devices, their self-management behavior and exacerbation-related outcomes. Participants' level of adherence may also have been influenced by the level of self-efficacy[18] and the different stages of grief in COPD, namely denial, resistance, sorrow, and acceptance.[19] Patients are unlikely to adhere to instructions and adapt new behavior in the stages preceding acceptance.[20]

For the current study, we performed secondary analyses on the RCT data[16] in order to explore the effects of adherence to the use of the mHealth tool on COPD exacerbation-related outcomes and self-management behavior when an exacerbation was imminent. We also explored differences in exacerbation-related self-efficacy and stages of grief between adherent and non-adherent patients,

Materials and Methods

Study Design

For this prospective study we used data from our multicenter, two-armed RCT that compared the effects of using the mHealth tool (intervention) with using a paper action plan (comparator) when COPD patients experienced flare-ups of respiratory symptoms.[16] We studied the effects of adherence to the use of the mHealth tool by using data from intervention group only.

Participants

The methods of the RCT have been described in detail elsewhere.[16] In short, inclusion criteria were: (1) age ≥ 40 years; (2) spirometry-confirmed diagnosis of COPD (postbronchodilator forced expiratory volume in 1 second (FEV1)/forced vital capacity <0.7); and (3) ≥2 symptom-based exacerbations in the past 12 months, defined as a change of ≥2 consecutive days with aggravation of two major symptoms (ie, dyspnea, sputum purulence, sputum amount) or an increase in 1 of the major symptoms plus the presence of ≥1 minor symptom (ie, cold, wheeze, sore throat, cough).[21] Exclusion criteria were (1) severe comorbid conditions; (2) insufficient knowledge of the Dutch language; and (3) persisting problems in using the mHealth system after a 2-week training period.[16]

Smart mHealth Tool

All participants in the information group of the RCT received a smart phone, a pulse oximeter (CMS50D, Contec Medical Systems, China), a spirometer (PiKo-1 monitor, nSpire, USA), and a forehead thermometer (FTN, Medisana AG, Germany). Patients answered 12 yes-or-no questions about changes in respiratory symptoms, physical limitations, emotions, and use of bronchodilators on the touch screen of the smartphone. They also entered measurements of blood oxygen level, FEV1, and forehead temperature.[16] All questions had to be answered to proceed. Based on the risk prediction of the built-in Bayesian network model,[14] the mHealth tool then provided one or more of the following advice: (1) increase the use of your bronchodilator; (2) use your breathing techniques; (3) use your coughing techniques; (4) be

thoughtful of how you distribute your energy; (4) contact your healthcare professional; (5) initiate your prescription of prednisolone and/or antibiotics; (6) measure again tomorrow. Using the system took approximately 5 minutes at a time.

Before the start of the RCT, participants received the instruction to use the system daily for 2 weeks to get familiarized with the smartphone, spirometer, pulse oximeter, and forehead thermometer. In this period, entries were monitored by the research team using a secured web-based interface to make sure participants practiced sufficiently. After this 2-week period, a respiratory nurse evaluated with the patient the use of the system and set reference values for FEV1 and blood oxygen level. Then, the follow-up started. Patients received the instruction to use the tool every time they experienced, or had any doubts about, any change in (respiratory) symptom or disease burden.

Outcomes and Measurements

A patient was considered adherent when during follow-up the patient had used the mHealth tool as intended in at least 50% of the experienced exacerbations, ie the patient had used the mHealth tool between 7 days before up to 3 days after the start date of an exacerbation. We used this range to include two exacerbation onset patterns: "sudden exacerbation onset", where the exacerbation start date was the same date as the day of symptom change, and "gradual exacerbation onset", where the exacerbation start date was preceded by a prodromal period of up to 7 days.[22]

Primary outcome was the difference in exacerbation-free weeks between patients who were adherent and those who were non-adherent to the use of the mHealth tool during the 12-months of follow-up. We defined a exacerbation-free week as a period of 7 days in which 2 major symptoms (or 1 major and 1 or more minor symptoms) did not aggravate for 2 or more consecutive days.[23]

Secondary outcomes were the difference between adherent and non-adherent mHealth tool users in self-management behavior and in prompt action. Patients received the advice to take one of the following self-management actions, depending on the severity of their symptoms: 1) increase the use of bronchodilators; 2) contact your healthcare professional; or 3) initiate your course of prednisolone/antibiotics. Prompt action was defined as the start of the self-management action within 3 days of the start of an exacerbation.

Changes in symptoms, self-management behavior and timing of self-management actions were measured in the RCT with the Telephonic Exacerbation Assessment System (TEXAS, Radboudumc).[24] TEXAS is a validated automated call system that contacts participants weekly. TEXAS consists of closed questions regarding changes in respiratory symptoms, healthcare utilisation, and use of respiratory medication in the week preceding the call. All data related to the use of the mHealth tool were recorded in a secured web-based interface during follow-up.

Exacerbation-related self-efficacy was measured in the RCT with a questionnaire including 5 questions on a 4-point Likert scale.[16] A higher total score meant a higher level of self-efficacy. We developed this questionnaire specifically for the RCT as, to our knowledge, there were no questionnaires available on exacerbation-related self-efficacy.[16] The questionnaire showed a Cronbach's alpha of 0.69 at baseline and 0.81 at 12-month follow-up.[16] We used the baseline data of the RCT in the current study.

Stages of grief were measured in the RCT with the Acceptance of Disease and Impairments Questionnaire (ADIQ), a valid and reliable instrument to measure denial, resistance, sorrow, and acceptance.[19] The ADIQ includes 14 questions on a 4-point Likert scale. A higher score on a subdomain means a higher presence of that specific stage of grief.[19] We used the baseline data of the RCT in the current study.

Statistical Analyses

Based on the TEXAS data, we calculated the timeframe of 7 days before and 3 days after exacerbation start date and combined this information with the mHealth tool data to assess intended use and adherence. We calculated the number of exacerbation-free weeks per patient as the total number of weeks without exacerbation occurrences during follow-up and as percentage of individual follow-up length in weeks. We expressed exacerbation-free weeks as the number of exacerbation-free weeks per patient per year and compared this between adherent and non-adherent patients using weighted rate ratios, thereby taking into account differences in length of follow-up time.[25] Self-management behavior and prompt action were assessed from the combined TEXAS and mHealth user data.

To compare baseline characteristics between adherent and non-adherent patients, we used the Fisher's exact test, the independent *t*-test or the Mann–Whitney *U*-test to compare nominal/ordinal, normally distributed continuous, and skewed continuous data, respectively. For the primary outcome we used generalized negative binomial regression analysis to compare the number of exacerbation-free weeks between both groups with correction for the length of follow-up, and the independent *t*-test to compare exacerbation-free weeks as percentage of follow-up length. For the secondary outcomes, self-management behavior and prompt action, we performed multilevel logistic regression analyses with correction for clustering of exacerbations within patients to compare adherent and non-adherent patients. Self-efficacy and stages of grief scores were compared using the independent *t*-test. Statistical significance was set at a two-sided p-value <0.05. IBM SPSS Statistics 25 was used for all analyses.

Results

Patient Characteristics at Baseline

From the 43 patients that were originally assigned to the intervention group in the RCT five patients were excluded who dropped out after randomization, but before the start of the follow-up. Reasons for drop-out were: difficulties with using the mHealth tool (n=1), having cognitive problems (n=1), correction of COPD into cardiac diagnosis by healthcare professional (n=1), and unknown reason (n=2).[16] Thus, we included data from 38 patients who had participated in the intervention group of the RCT in the current study. Two of the 38 patients did not complete the 12-month follow-up due to death (n=1) or severe comorbidities (n=1). Table 1 shows baseline characteristics of adherent (n=13) and non-adherent (n=25) patients. None of the baseline characteristics differed statistically significant between adherent and non-adherent mHealth tool users.

Table 1 Baseline Characteristics of Adherent and Non-Adherent Users of the COPD Exacerbation mHealth Tool (n=38 Patients in Total)

	Adherent Users	Non-Adherent Users	P-value
N (%)	13 (34.2)	25 (65.8)	-
Male, n (%)	5 (38.5)	15 (60.0)	0.31
Age in years, mean (SD)	69.22 (11.16)	68.67 (7.81)	0.86
BMI, mean (SD)	29.84 (4.02)	26.20 (6.21)	0.11
Having a partner, n (%)	10 (76.9)	19 (76.0)	0.95
FEV1 post BD, mean (SD)	1.36 (0.62)	1.57 (0.71)	0.78
CCQ total score, mean (SD)	1.83 (0.94)	2.03 (1.05)	0.56
MRC dyspnea score ≥ 3, n (%)	6 (46.2)	12 (48.0)	0.74
Diagnosis COPD > 5 years, n (%)	7 (53.8)	17 (68.0)	0.49
Currently smoking, n (%)	3 (23.1)	9 (36.0)	0.49
Low educational level, n (%)	6 (46.2)	9 (36.0)	0.67
Short-acting bronchodilators, n (%)	9 (69.2)	16 (64.0)	0.75
Long-acting bronchodilators, n (%)	8 (61.5)	13 (52.0)	0.73
Inhaled corticosteroids, n (%)	3 (23.1)	1 (4)	0.11
Long-acting bronchodilators plus inhaled corticosteroids, n (%)	9 (69.2)	11 (44.0)	0.18
Number of self-reported exacerbations in 12 months prior to study, mean (SD)	3.15 (1.07)	2.96 (1.14)	0.61

Abbreviations: BMI, Body Mass Index; FEV1 post BD, Forced Expiratory Volume in one second post bronchodilator; CCQ, Clinical COPD Questionnaire; MRC, Medical Research Council.

Exacerbations and Adherence to the mHealth Tool

Table 2 shows the differences in exacerbation-free weeks between adherent and non-adherent users of the mHealth tool. The mean (SD) total follow-up time did not differ between adherent and non-adherent users (51.1 (5.9) versus 51.7 (5.2), p=0.78). Although adherent users showed a trend towards fewer exacerbations per year during follow-up than non-adherent users (mean (SD) 3.4 (1.5) versus 4.7 (2.1) exacerbations per patient per year, respectively), the difference in exacerbation frequency was not statistically significant (p=0.07). The frequency of mHealth tool use in the group of adherent users was higher than in the group of non-adherent users, but its range was wide and varied from 3 to 250 times during follow-up. The number of exacerbation-free weeks did not differ statistically significant between adherent and non-adherent users of the mHealth tool (mean (SD) 31.5 (14.5) versus 33.5 (10.2), p=0.63). In both groups, more than 60% of follow-up time, patients were free of exacerbations.

Self-Management Behavior and Prompt Action

Table 3 presents differences in self-management behavior and prompt action between adherent and non-adherent users of the mHealth tool. Adherent users did not differ statistically significant from non-adherent users in type of self-management actions and timing of these actions. Adherent patients increased their bronchodilator use in almost 82% of the exacerbations they experienced, compared to 65.5% in non-adherent patients (OR 2.51, 95% CI 0.80 to 7.86). Also, adherent users contacted their healthcare professional and initiated a course of prednisolone and/or antibiotics in more exacerbations compared to non-adherent users (OR 1.60, 95% CI 0.62 to −4.11 and OR 2.36, 95% CI 0.73 to 7.59,

Table 2 Effect of Adherence to the COPD Exacerbation mHealth Tool on Exacerbation-Free Weeks

	Adherent Users	Non-Adherent Users	p-value
N (%)	13 (34.2)	25 (65.8)	
Follow-up weeks, mean (SD)	51.1 (5.9)	51.7 (5.2)	0.78
Number of exacerbations per patient per year, mean (SD)	3.4 (1.5)	4.7 (2.1)	0.07
Frequency of mHealth tool use during follow-up, median (range)	26 (3–250)	6 (0–17)	0.002
Number of exacerbation-free weeks, mean (SD)	31.5 (14.5)	33.5 (10.2)	0.63
Number of exacerbation-free weeks as percentage of follow-up length, mean (SD)	60.6 (28.0)	64.5 (19.7)	0.63

Table 3 Self-Management Behavior and Prompt Treatment in Adherent and Non-Adherent Users of the COPD Exacerbation mHealth Tool

	Adherent Users n=13	Non-Adherent Users n=25	OR (CI 95%)	p-value
Number of exacerbations …	44	116	–	–
… in which bronchodilator use was increased, n (%)	36 (81.8)	76 (65.5)	2.51 (0.80–7.86)	0.11
… in which bronchodilator use was increased promptly, n (%)	28 (63.6)	58 (50)	1.76 (0.66–4.70)	0.26
… in which healthcare professional was contacted, n (%)	16 (36.4)	32 (27.6)	1.60 (0.62–4.11)	0.33
… … in which healthcare professional was contacted promptly, n (%)	6 (13.6)	16 (13.8)	1.03 (0.31–3.44)	0.96
… in which a course of prednisolone and/or antibiotics was used, n (%)	19 (43.2)	30 (25.9)	2.36 (0.73–7.59)	0.15
… in which a course of prednisolone and/or antibiotics was used promptly, n (%)	10 (22.7)	12 (10.3)	2.91 (0.65–13.12)	0.16

respectively). In almost 23% of the exacerbations, adherent patients initiated a course of prednisolone and/or antibiotics within 3 days of exacerbation onset, compared to 10% in non-adherent users (OR 2.91, 95% CI 0.65–13.12).

Self-Efficacy and Stages of Grief

Table 4 displays mean (SD) scores on self-efficacy and stages of grief in adherent and non-adherent users. Mean scores of self-efficacy and disease acceptance were higher and mean scores of denial, resistance, and sorrow were lower in adherent users compared to non-adherent users. Overall, we found no statistically significant differences in mean scores between the two groups.

Discussion

We performed secondary analyses on data of a recent RCT to explore the effects of mHealth adherence on COPD exacerbation-related outcomes and self-management behavior. We also explored whether self-efficacy and stages of grief differed between adherent and non-adherent users. We found no statistically significant differences between adherent and non-adherent users in exacerbation-free weeks. However, compared to non-adherent users, it seemed that adherent users took more self-management actions and more actions promptly when an exacerbation was imminent, we found no statistically significant differences between both groups. Adherent users seemed to have higher scores of self-efficacy and disease acceptance and lower scores of denial, resistance and sorrow when compared to non-adherent users (but again, not statistically significant).

This is the first study that explored the effects of adherence to an mHealth tool for COPD exacerbation self-management. The mHealth tool was developed to better support patients in recognizing of and timely responding to COPD exacerbations. In the recent RCT, we found no benefits of the mHealth tool compared with a paper action plan on exacerbation-related outcomes.[16] In our current study, we focused on the RCT intervention group to assess the effects of adherence to the mHealth tool. We could not demonstrate any statistically significant differences between adherent and non-adherent users on exacerbation-free weeks. Previous studies found a faster exacerbation recovery time – which implicates more exacerbation-free weeks – when patients were adherent to their paper action plan.[9,26] Farias et al found that in 72% of the exacerbations at least one of the self-management actions was taken within 3 days of symptom worsening.[26] We found that adherent patients increased their bronchodilator use in almost 82% of the exacerbations and did this within 3 days of exacerbation start in 64% of the exacerbations.

We hypothesized that adherence to the mHealth tool would exceed adherence to paper action plans through personalizing self-management support more efficiently and continuously. We found that around 34% of the patients in the RCT mHealth group could be considered as adherent. This is slightly lower when compared with adherence rates around 40% in studies on paper exacerbation action plans.[9,27] We are not aware of other published studies describing the level of adherence to mHealth in relation to health outcomes in other chronic diseases. According to COPD patients,

Table 4 Differences in Scores on Self-Efficacy and Stages of Grief Between Adherent and Non-Adherent Users of the COPD Exacerbation mHealth Tool

	Adherent Users, n=13	Non-Adherent Users, n=25	p-value
Self-efficacy[a], mean (SD)	3.03 (0.43)	2.89 (0.39)	0.34
Denial[b], mean (SD)	2.17 (0.63)	2.33 (0.78)	0.54
Resistance[b], mean (SD)	1.56 (0.64)	1.81 (0.75)	0.32
Sorrow[b], mean (SD)	1.33 (0.33)	1.44 (0.56)	0.53
Acceptance[b], mean (SD)	3.06 (0.79)	2.6 (0.86)	0.12

Notes: [a]Self-efficacy was measured with an exacerbation-related self-efficacy scale containing 5 questions on a 4-point Likert scale. A higher total score means a higher level of self-efficacy.[b]Denial, resistance, sorrow, and acceptance were measured with the Acceptance of Disease and Impairments Questionnaire (ADIQ), which includes 14 questions on a 4-point Likert scale. A higher score on a subdomain means a higher presence of that specific stage of grief.

mHealth interventions should add value to the regular contacts with healthcare professionals. Commitment with mHealth could be further improved by making mHealth interventions attractive, rewarding and safe.[28] Educating patients may also facilitate mHealth adoption, whereas technical issues, lack of awareness, and privacy issues can be important barriers.[29] A recent systematic review on factors influencing adherence to mHealth for the management of noncommunicable diseases revealed that, next to intervention-related factors, low adherence was associated with technical incompetence, health illiteracy, and inexperience with mHealth apps.[30] In our RCT, patients used the tool daily for two weeks to become experienced. They were excluded from trial participation if they still showed difficulties in using the mHealth tool. Unfortunately, we did not assess health literacy in our RCT participants. Patients in the mHealth tool group valued the tool as more helpful than patients using the paper action plan and appraised its usability as high.[16] Qualitative interviews with non-adherent users could have provided us with relevant information on perceptions and barriers of mHealth tool use but were not conducted. To our knowledge, this is the first study to show that the levels of self-efficacy and disease acceptance seemed higher in patients who were adherent to the mHealth tool than those who were not. Although these differences were not statistically significant and should therefore be interpreted with caution, it is remarkable that the levels of denial, resistance, and sorrow all were higher in patients who were not adherent to mHealth.

Using the data of our RCT on the effects of an mHealth intervention on COPD-related outcomes enabled us to explore the effects of adherence to this mHealth tool. Combining usage data, automatically recorded in a web-based interface during follow-up, with data on symptom worsening and self-management behavior, collected through the automated telephone call system TEXAS, enabled us to compile and analyze a very detailed dataset. However, our results should be interpreted with caution. Since we performed secondary analyses on a small sample of patients, it can be questioned whether we had enough power to detect statistically significant differences between adherent and non-adherent patients. Also, the cut-off value that we used for our definition of adherence (ie the patient had to have used the mHealth as intended in at least 50% of the experienced exacerbations) was based on expert opinion rather than scientific literature. Adherence is recognized as a difficult and ill-defined concept in studies on mHealth.[31] When defining adherence in our study we followed the three elements as proposed by Sieverink et al, namely: (1) the ability to measure the actual usage by patients; (2) an operationalization of intended use; and (3) a rationale of the intended use.[31]

Conclusion

Adherence to mHealth may be positively associated with COPD exacerbation self-management behavior, self-efficacy and disease acceptance, but its association with exacerbation-free weeks remains unclear. Our results should be interpreted with caution due to the study's explorative nature and small sample size. Our study should be considered as a pilot study. It may serve as first step towards well-designed studies with sufficient power to confirm our findings.

Data Sharing Statement

The data that support the findings of this study are available for access via the corresponding author upon reasonable request.

Ethics Approval

This study was conducted in accordance with the Declaration of Helsinki of the World Medical Association. We used data of an RCT that has been registered at ClinicalTrials.gov (Identifier: NCT02553096). The medical ethics review board, region Arnhem-Nijmegen, the Netherlands, has approved the trial under file number 2014–1270. All participants in the trial provided written informed consent before randomisation.

Author Contributions

All authors made a significant contribution to the work reported, either in the study idea, design, execution, data collection, analysis and interpretation, or in all these areas. All authors have drafted or written, or substantially revised or critically reviewed the article. All authors have agreed on the journal to which the article will be submitted. All authors reviewed and agreed on the article before submission, during revision, the final version accepted for publication, and any

significant changes introduced at the proofing stage. All authors agree to take responsibility and be accountable for the contents of the article.

Disclosure

The authors report no conflicts of interest in this work.

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