A Randomized Controlled Trial of a Literacy-Sensitive Self-Management Intervention for Chronic Obstructive Pulmonary Disease Patients

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BACKGROUND: Low literacy skills are common and associated with a variety of poor health outcomes. This may be particularly important in patients with chronic illnesses such as chronic obstructive pulmonary disease (COPD) that require appropriate inhaler technique to maintain quality of life and avoid exacerbations.
OBJECTIVE: To explore the impact of a literacy-sensitive self-management intervention on inhaler technique scores in COPD patients and to determine if effects differ by literacy.
DESIGN: Randomized controlled trial.
PARTICIPANTS: Ninety-nine patients with COPD.
INTERVENTION: Patients were randomly assigned to a one-on-one self-management educational intervention or usual care. The intervention focused on inhaler technique, smoking cessation, and using a COPD action plan.
MAIN MEASURES: At baseline, an inhaler technique assessment, literacy assessment, health-related quality of life questionnaires, and pulmonary function tests were completed. Inhaler technique was re-evaluated after two to eight weeks.
KEY RESULTS: Mean age 63, 65% female, 69% Caucasian, moderate COPD severity on average, 36% with low literacy, moderately impaired health-related quality of life, and similar baseline metered dose inhaler technique scores. Patients in the intervention group had greater mean improvement from baseline in metered dose inhaler technique score compared to those in the usual care group (difference in mean change 2.1, 95% CI 1.1, 3.0). The patients in the intervention group also had greater mean improvements in metered dose inhaler technique score than those in the usual care group whether they had low health literacy (difference in mean change 2.8, 95% CI 0.6, 4.9) or higher health literacy (1.8, 95% CI 0.7, 2.9).
CONCLUSIONS: A literacy-sensitive self-management intervention can lead to improvements in inhaler technique, with benefits for patients with both low and higher health literacy.

KEY WORDS: COPD; inhaler technique; health literacy; self-management; randomized controlled trial.
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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common chronic illness with an associated cost[1,2]. Inadequate literacy skills are common and associated with increased risk for mortality, hospitalization, and poor disease control[3–7]. Literacy may play an important part in controlling COPD. since it requires effective self-management skills and navigation of the health care system to maintain quality of life and avoid life-threatening exacerbations. Self-management can be challenging and to address the increasing prevalence, economic burden, and need to improve outcomes, guidelines for the management of COPD have focused on improving self-management skills and patient education[8].

Patients with COPD are often prescribed several inhalers, including pressurized metered dose inhalers (MDIs) and breath actuated dry powder inhalers (DPIs); each requiring very different inhalation techniques. Poor inhaler technique is common and significantly limits drug delivery to the lungs[9]. Correct administration of these inhaled medications is very important for successful management of COPD. Further, studies of subjects with asthma found those with inadequate literacy have lower medication knowledge and worse inhaler technique scores than those with adequate literacy[10,11]. Multiple COPD self-management interventions that focused on disease-specific health education, including inhaler technique education, have shown improvement in health care utilization, health-related quality of life, and use of rescue medications[12–14]. However, whether the efficacy of these interventions differs between patients with low and higher literacy is not known. In this study, we aimed to test the impact of a literacy-sensitive, multicomponent self-management intervention on inhaler technique scores of COPD patients and to determine if its effects differ by literacy.

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METHODS

We conducted a randomized controlled trial in an academic general internal medicine practice (University of North Carolina, Chapel Hill, NC) between January 2008 and July 2009. The study was approved by the University's Institutional Review Board. Participants were screened for eligibility if they had: (1) active prescription for an inhaled medication, (2) order for inhaled medication on the inpatient service, or (3) diagnosis of COPD (billing data). To be included, participants had to be adult, English speaking with a diagnosis of COPD, chronic bronchitis, or emphysema being treated with an inhaled medication at our practice. We excluded patients who were experiencing an exacerbation of their COPD at the time of recruitment or who only had asthma. Patient's were electronically screened by medical record and verbally screened for inclusion criteria prior to enrollment.

Enrolled participants completed baseline assessments including spirometry, baseline questionnaire, the Short Test of Functional Health Literacy in Adults (S-TOFHLA)[15,16], the St. George's Respiratory Questionnaire (SGRQ)[17], and inhaler technique using our eight item checklists. Following baseline assessment, participants were randomized 2-to-1 to the intervention or usual care group. We used a computer-generated randomization sequence, which was generated prior to enrollment by an investigator who was not involved in recruitment or outcome assessment.

The intervention included a one-on-one education session which utilized a literacy-sensitive handout titled Living With COPD (online Appendix 1). The handout's readability, ability to enhance the reader's self-efficacy, and cultural appropriateness was rated superior (score of 81%, range 0% to 100%) per the Suitability Assessment of Materials which is a validated instrument that systematically and objectively assesses the suitability of health information[18]. The readability was rated adequate and at the 7th grade reading level per the Suitability Assessment of Materials and the SMOG Formula[18,19]. A research assistant (RA) was trained to perform study enrollment, assessment, intervention, and follow-up. He completed training to become a certified spirometry technician and received eight hours of one-on-one intervention and inhaler technique training from a pharmacist and physician. To maintain fidelity, the RA followed scripts and a written protocol for all study procedures. For the intervention, the RA verbally went through the handout focusing on main concepts and teaching points. A "teach-back" method was used to ensure appropriate communication of the material[20]. To demonstrate appropriate inhaler technique, our RA showed each subject the illustrations of appropriate technique and then demonstrated appropriate use using a placebo inhaler. The RA then asked each subject to demonstrate appropriate use. For any steps they performed incorrectly, the RA would again demonstrate and describe appropriate use, until they were able to do all steps correctly. The usual care group completed all baseline assessments, but did not receive inhaler technique training and received no educational materials beyond those provided as part of their usual clinical care. The educational sessions were 15 to 30 minutes in length.

Participants in both the usual care and intervention groups returned for follow-up assessments after 2 to 8 weeks. The flexible follow-up timeline was due to scheduling variability of the participant and study RA and to optimize the study completion. Follow-up measures included a follow-up questionnaire and repeating the inhaler technique assessment. Participants received a $20 gift card for completing baseline and follow-up assessments.

Measures

All assessments, with the exception of the S-TOFHLA, were verbally administered by the RA. The RA conducted baseline spirometry on all enrolled participants and recorded actual and percent predicted for FEV_1, FVC, and FEV_1/FVC ratio. The baseline questionnaire included questions about basic demographic information.

The Short Test of Functional Health Literacy in Adults[15,16] (S-TOFHLA) is a validated, self-administered instrument used to measure reading comprehension. It uses the Cloze procedure, which omits a word or words from a sentence and the participant must choose the omitted word(s) from a list. It uses health-related materials such as consent forms to assess participant's ability to understand written materials. Scores for the S-TOFHLA range from 0 to 36 and are categorized as inadequate literacy (0 to 16), marginal literacy[17–22], and adequate literacy (23 to 36). For the purposes of our study, we combined the marginal and inadequate groups to form our low literacy group (those with a score from 0 to 22).

The St. George's Respiratory Questionnaire[17] (SGRQ) is a validated instrument designed to measure disease-specific health-related quality of life. It utilizes items on a 5-point Likert scale and a dichotomous (true/false) scale. The scale ranges from 0 (representing the best) to 100 (representing the worst) possible health status.

Inhaler technique assessments were conducted for any of the following inhaler types: metered dose inhaler (MDI), MDI with spacer, Diskus® dry powder inhaler, and Handihaler® dry powder inhaler. We chose these inhaler types because they were the most commonly used in our population. Using placebo inhalers, participants demonstrated how they would normally administer two puffs of their MDI and one dose of their Diskus® and/or Handihaler®, as applicable. The RA observed and scored each participant's inhaler technique using our eight item checklist (Table 1). This inhaler technique checklist was developed due to a lack of consensus in the literature on what items should be assessed for various inhaler techniques. Our checklist is based on technique descriptions from product package inserts, expertise of the study investigators in what items should be included, and a review of the literature of previously used inhaler technique checklists, including national guidelines[10,21–29]. The checklists are each comprised of eight items which were assessed as appropriate for the use of the inhaler and were all necessary elements and to keep each as discrete, assessable items. The participant would have to correctly perform each step to receive each point. We performed inter-rater reliability on a subset of 10 subjects, observed simultaneously by two assessors. Agreement ranged from 70-100% for the eight items (mean 82.5% agreement, kappa 0.64).

STATISTICAL ANALYSIS

The primary outcome was change in mean MDI (without spacer) technique score from baseline. We calculated that we would need to enroll at least 36 subjects with low literacy, which would require around 100 total subjects (depending on

Table 1. Inhaler Technique Score Checklists

Metered Dose Inhaler (MDI)	1. Remove cap 2. Shake the inhaler 3. Breathe out completely 4. Place inhaler 1–2 inches away from mouth OR in mouth and close lips tightly around mouthpiece 5. Activate the MDI* at the start of inhalation 6. Slowly and deeply breathe in 7. Hold breath for 10 seconds or as long as possible 8. Wait at least 1 minute before repeating steps 3 through 8
Metered Dose Inhaler (MDI) with spacer	1. Remove cap 2. Shake the inhaler and then insert mouthpiece of inhaler into the spacer 3. Breathe out completely 4. Close lips tightly around mouthpiece of spacer 5. Activate the MDI and then start inhalation 6. Slowly and deeply breathe in (should only hear a light whistling sound) 7. Hold breath for 10 seconds or as long as possible 8. Wait at least 1 minute before repeating steps 3 through 8
Diskus®	1. Open inhaler by pushing the thumb grip away from mouthpiece until it clicks 2. Hold inhaler level with ground 3. Slide lever away until it clicks to prepare dose 4. Breathe out completely away from device 5. Close lips tightly around mouthpiece 6. Breathe in deeply 7. Hold breath for 10 seconds or as long as possible 8. Rinse mouth with water and spit out
Handihaler®	1. Open the inhaler device and the capsule blister 2. Insert the capsule into the inhaler and close mouthpiece 3. Hold inhaler with mouthpiece upwards 4. Press green button once to prepare dose 5. Breathe out completely away from device 6. Close lips tightly around mouthpiece 7. Breathe in deeply (should hear capsule vibrate) 8. Hold breath for 10 seconds or as long as possible

**MDI: Metered Dose Inhaler*

the prevalence of low literacy in the study population). We based this sample size calculation on detecting a 2-point improvement in mean MDI technique scores (zero to eight scale) in the intervention group compared to the control group, 2:1 randomization to the intervention group, 80% power, standard deviation of 2, and an alpha of 0.05. We used a 2-point improvement based on the results of a study in asthma subjects[11] that found about a 1.5 point difference on a 6-point scale in inhaler technique scores between the lowest literacy group and the highest literacy group. We reasoned that since our scale was an 8 point scale, that finding a 2-point difference was reasonable. We conducted separate analyses for different inhaler types (i.e. Diskus® and Handihaler®); these were pre-specified, but the study was not powered for these smaller groups. Only a few enrolled subjects used an MDI with a spacer, therefore, we were unable to conduct meaningful analyses on these data. We used t-tests to compare mean change in scores between those in the intervention and control groups. For our analyses, we stratified the intervention and control groups by literacy and used t-tests to compare mean change in scores for those with low and higher literacy.

RESULTS

Baseline

Ninety-nine subjects were enrolled, 67 were randomized to the intervention group and 32 to the usual care group (Fig. 1). Mean age of enrolled subjects was 63, 65% female, 69% Caucasian, and the mean FEV1 % predicted was 55, indicating moderate COPD (Table 2). Overall, characteristics were similar between the intervention and usual care groups except for some differences in education, with those in the control group having a higher percentage of subjects in the lowest education group. Non-completers of the study were more likely to be Caucasian, male, and have low health literacy.

Baseline MDI inhaler technique scores were similar between intervention and usual care groups (5.2 vs. 5.6, p=0.29) (Table 3). Patients with low literacy had slightly lower MDI technique scores, but the difference was not statistically significant (4.9 vs. 5.5, p=0.09).

MDI

Table 3 and online Appendix 2 shows data for all inhaler technique scores by inhaler type. The intervention group had a mean 2.1 (95% CI: 1.1, 3.0) point greater improvement in MDI

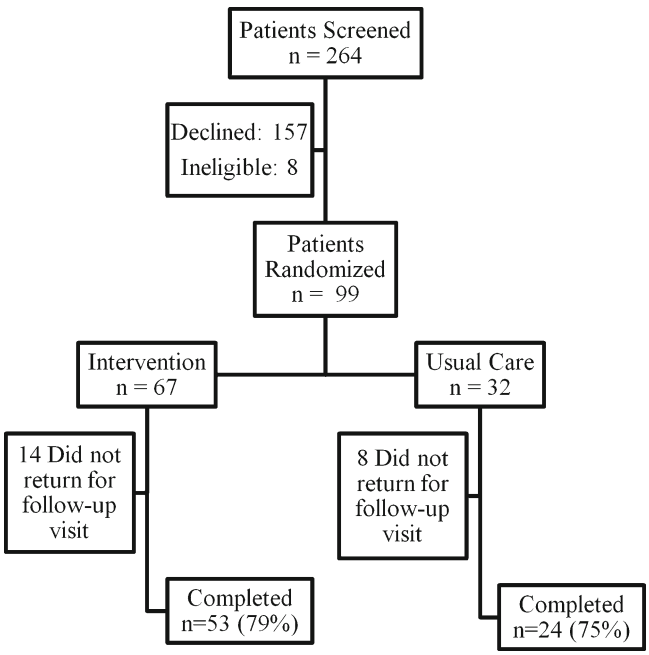

Figure 1. Study flow diagram.

Table 2. Baseline Characteristics

	Overall	Intervention	Usual Care
N	99	67	32
Mean age (range)	63 (43–84)	63 (43–84)	63 (44–83)
African American (%)	29	30	28
Caucasian (%)	69	67	72
Female (%)	65	64	66
Insured (%)	93	91	97
Annual household income (%)			
< $15,000	51	52	50
$15,000 to $29,999	26	27	22
$30,000 or greater	23	21	28
Education (%)			
≤11th grade	31	27	40
High School grad or GED*	29	30	28
Some college	39	42	31
Low Health Literacy† (%)	36	37	33
SGRQ‡ score mean (SD), range	52.6 (15.8), 19-88	54.4 (15.9)	48.7 (15.1)
FEV1§ % Predicted, mean (SD)	54.8 (19.5)	53.6 (20.4)	57.6 (17.2)
Use of Oxygen (%)	26	30	19

GED: general equivalency diploma; †Health literacy determined using Short-Test of Functional Health Literacy in Adults scores; ‡SGRQ: St. George's Respiratory Questionnaire; §FEV1: Forced Expiratory Volume in 1 second

technique scores than the usual care group. Time to follow-up did not significantly affect the change in MDI inhaler technique score from baseline (p=0.39). When analyzing by literacy subgroup, patients with low literacy had greater mean benefit from the intervention than those with higher literacy, but the difference in the improvement scores was not statistically significant (1.8 vs. 1.5; p=0.63). Low literacy subjects in the intervention group had a mean 2.8 (95% CI: 0.6, 4.9) point greater improvement in MDI technique scores than low literacy subjects in the usual care group. Higher literacy subjects in the intervention group had a mean 1.8 (95% CI: 0.7, 2.9) point greater improvement in MDI technique scores than higher literacy subjects in the usual care group.

The proportion of participants in the intervention group scoring 7 or 8 out of 8 points increased significantly after the intervention from 21.4% to 66.7% (p=0.002). There was no significant change in the usual care group from 29.6% to 23.5%. Three inhaler technique steps were commonly performed incorrectly at baseline. These included breathing out completely prior to inhaling the medication (86%), holding one's breath for a sufficient time after inhaling the medication (50%), and waiting at least 1 minute before taking a second puff (66%). For the intervention group, the percent of participants correctly performing each of these items improved after the intervention, but there were no significant changes in the usual care group (online Appendix 3).

Diskus®

Of enrolled subjects, 41 were using a Diskus® inhaler. There was no significant difference between intervention and usual care groups for change in inhaler technique scores for Diskus®, but there was a trend toward greater improvement in the intervention group (0.9 vs. 0.4, p=0.18) (Table 3). When analyzing by literacy subgroup, the mean improvement in inhaler technique score within the intervention group was significantly greater in low literacy subjects than higher literacy subjects (1.75 vs. 0.63, p=0.02). The proportion of participants in the intervention group scoring 7 or 8 out of 8 points increased significantly after the intervention from 43.7% to 92.6%. Three inhaler technique steps were commonly performed incorrectly. These included breathing out completely away from the device prior to inhalation (75%), holding one's breath for a sufficient time after inhaling the medication (44%), and rinsing one's mouth with water after using the inhaler (28%). For the intervention group, the percent of participants correctly performing each of these items improved after the intervention, but there were no significant changes in the usual care group.

Handihaler®

Of enrolled subjects, 27 were using a Handihaler®. Participants in the intervention group had greater mean improvements from baseline in Handihaler® technique scores than those in the usual care group, but the difference was not statistically significant (0.71 vs. 0.09, p=0.14) (Table 3). When analyzing by literacy subgroup, improvements were similar for each literacy group. The proportion of participants in the intervention group scoring 7 or 8 out of 8 points increased significantly after the intervention from 45% to 93.3%; there

Table 3. Mean Inhaler Technique Score at Baseline and Follow-up

Inhaler	Usual Care				Intervention				Difference in Mean Change (95% CI)	p value
	N	Baseline Score	Follow-up Score	Mean Change	N	Baseline Score	Follow -up Score	Mean Change		
MDI* Overall	32	5.6	5.2	−0.5	67	5.2	6.7	1.6	2.1 (1.1, 3.0)	<0.001
Low Literacy		5.2	4	−1.0		4.8	6.3	1.8	2.8 (0.6, 4.9)	0.015
Higher Literacy		5.8	5.5	−0.3		5.4	6.9	1.5	1.8 (0.7, 2.9)	0.001
Diskus® Overall	14	6.0	6.6	0.43	27	6.0	7.3	0.96	0.53 (−0.25, 1.3)	0.18
Low Literacy		5.8	7.3	1.0		5.1	7.4	1.75	0.75 (−1.1, 2.6)	0.39
Higher Literacy		6.0	6.4	0.27		6.6	7.2	0.63	0.36 (−0.48, 1.2)	0.39
Handihaler® Overall	11	6.6	6.7	0.09	16	6.1	7.3	0.71	0.62 (−0.2, 1.5)	0.14
Low Literacy		6	7	0		5.1	7.3	1.25	–	–
Higher Literacy		6.6	6.7	0.1		6.7	7.4	0.5	0.4 (−0.6, 1.4)	0.4

MDI: metered dose inhaler

was no change in the usual care group (57.2% to 63.7%). Three inhaler technique steps were commonly preformed incorrectly. These included breathing out completely away from the device prior to inhalation (90%), breathing in deeply when inhaling the medication (30%), and holding one's breath for a sufficient time after inhaling the medication (45%). For the intervention group, the percent of participants correctly performing each of these items improved after the intervention, but there were no significant changes in the usual care group.

DISCUSSION

Our study demonstrates that a literacy-sensitive intervention which is comprised of a 30 minute one-on-one session utilizing a step-by-step handout and the "teach-back" method can lead to improvements in inhaler technique in patients with COPD, with similar benefits for patients with both low and higher literacy. Disease management programs which include education on inhaler technique can effectively improve appropriate use of MDI, Diskus®, and Handihaler® devices in patients with low literacy.

Overall, subjects in both the intervention and usual care groups performed the worst on one item-breathing out completely before inhalation. At baseline there were 80% to 90% of subjects, depending on the type of inhaler, who incorrectly performed this item. A recent study of hospitalized patients with COPD or asthma reported similar findings, with over 75% of subjects missing breathing out completely before inhalation[30]. Another study reported over 60% of patients with asthma or COPD incorrectly performing this step[31]. Other studies have reported overall rates of inhaler misuse from 30% to 100% of patients[10,26,32]. Even after our intervention, the percent of subjects who incorrectly performed this item still ranged from about 30% (Handihaler®) to 50-60% (Diskus® and MDI). This suggests that our intervention did not adequately teach this step or that it is more difficult than other steps to teach, learn, or perform. After the intervention, all other steps were performed incorrectly by fewer than 20% of subjects.

The second item most commonly performed incorrectly was holding one's breath for a sufficient amount of time after inhaling the medication. At baseline there ranged between 40% (Handihaler®) and 60% of subjects (MDI) performing the item incorrectly. A prior study of patients with asthma or COPD found similar results, with over 50% of subjects unable to hold their breath for at least 5 seconds[31]. In our study, all subjects missing this item were holding their breath for only 1–2 seconds and were not missing this item due to being only a few seconds short of the 10-second goal. In the intervention group, ability to perform this item improved, with just 10-20% of subjects performing incorrectly at follow-up.

Although we did not find statistically significant differences in improvement between low and higher literacy groups for MDIs, there was a clear trend toward greater improvement among patients with low literacy compared to those with higher literacy; we did find a statistically significant difference in improvement favoring low literacy subjects for Diskus®. These findings are consistent with an asthma education study which demonstrated greater knowledge improvements and MDI technique for patients with low literacy[10]. Another recent study of hospitalized patients with asthma or COPD documented that patients with low literacy did not have worse inhaler use at baseline than those with higher literacy, and were able to learn how to master inhaled medications after a literacy-sensitive intervention[30]. In our study, we observed mastery during the education session, but upon reevaluation some of the inhaler steps were not completed correctly. This finding suggests that even once patients master a skill, there may be incomplete retention of a multi-step processes such as inhaler use.

Our study has some limitations. We did not collect characteristic data for those participants that did not participate in the study. This could decrease the generalizability of the study findings. Also, our research assistant was not masked. This could introduce bias into the research assistant's interpretation of the subject's inhaler technique assessment. The research assistant was trained by our team in the proper inhaler technique for each of the inhalers that were assessed. The inhaler technique item checklist was specifically developed for this study and is not validated; however inter-rater reliability was good (kappa 0.64) for the subset of subjects that we used to assess it. At the time of the study design, there were no universally accepted or validated instruments to measure technique scores for the inhaler types that we were assessing. The checklists that we used were compiled from many literature sources as described in the Measures section. The time line for follow-up was between 2 and 8 weeks after randomization. This variability in time could have lead to an attenuation of intervention effect for those who had longer follow-up. However, time to follow up did not significantly affect the results of our analyses. Finally, this study was not powered to detect small differences for Diskus® or Handihaler®.

In conclusion, a literacy-sensitive intervention can lead to improvements in inhaler technique, with similar benefits for patients with both low and higher literacy. This intervention is brief, focused, and feasible for a variety of trained physician extenders to perform in the outpatient setting. Further evaluation is needed to determine whether similar interventions affect clinical health outcomes such as emergency room visits, frequency of exacerbations, health-related quality of life, and mortality.

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Conflict of Interest: *None disclosed.*

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