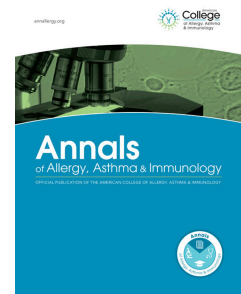


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A behavioral intervention can decrease asthma exacerbations in older adults

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PII: S1081-1206(19)31493-0

DOI: <https://doi.org/10.1016/j.anai.2019.12.015>

Reference: ANAI 3107

To appear in: *Annals of Allergy, Asthma and Immunology*

Received Date: 6 November 2019

Revised Date: 8 December 2019

Accepted Date: 12 December 2019

Please cite this article as: Baptist AP, Hao W, Song PX, Carpenter L, Steinberg J, Cardozo LJ, A behavioral intervention can decrease asthma exacerbations in older adults, *Annals of Allergy, Asthma and Immunology* (2020), doi: <https://doi.org/10.1016/j.anai.2019.12.015>.

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Title: A behavioral intervention can decrease asthma exacerbations in older adults

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Conflict of Interest: The authors declare no conflicts of interest

Funding source: NIH / National Institute on Aging - R01 AG043401 to Alan P. Baptist

Clinical Trials Registration: NCT01979055

Keywords: asthma; older adults; asthma exacerbations; behavioral interventions; self-regulation; education

Abbreviations: Emergency Department – ED
Body mass index – BMI
Asthma Control Test – ACT
Asthma Quality of Life Questionnaire – AQLQ
Perceived Control of Asthma Questionnaire – PCAQ
Fraction of exhaled nitric oxide – FENO
Chronic obstructive pulmonary disease – COPD

Word Count: 2772

Figures: 3

Tables: 2

19-11-0548R1

Background: Older adults have higher rates of asthma morbidity and mortality compared to younger age groups. There are few interventions tailored to this population.

Objective: To evaluate a self-management asthma intervention in older adults.

Methods: Adults age 55 and above with persistent asthma were enrolled into blinded, randomized controlled trial of a 6-session asthma self-management intervention. This educational intervention was conducted in group sessions and through individual telephone calls. Outcomes including asthma exacerbations (defined as unscheduled office visits, emergency department visits, or hospitalizations for asthma), spirometric values, FeNO, asthma control, asthma quality of life, and asthma self-management were assessed at 3, 6, and 12 months.

Results: 189 subjects were enrolled, 172 were randomized and received at least one treatment dose, and 145 (84%) were analyzed at 12 months. On a modified intent to treat analysis, those in the intervention group were less likely to have an asthma exacerbation (26.9% vs 47.1%, $p = 0.01$), had a lower asthma exacerbation rate (0.8 vs 1.9, $p = 0.02$), had better asthma control (19.9 vs 18.6, $p = 0.08$) and had a higher asthma self-management score (8.9 vs 8.4, $p = 0.03$). After a mixed model analysis to control for confounding factors, a decrease in asthma exacerbations ($p = 0.02$), as well as a decreased asthma exacerbation rate ($p = 0.04$), remained statistically significant while asthma control and self-management did not. No other significant outcome differences were found.

Conclusion: A 6 session asthma self-management intervention can successfully decrease asthma exacerbations among older adults.

Introduction

Asthma has been frequently overlooked in the geriatric population. Physicians and patients often erroneously believe asthma is a disease that only affects children, or that all asthma begins in childhood. However, studies show that up to 40% of adults with asthma have their first attack after the age of 40.^{1,2} Under-diagnosis and delayed initiation of care for asthma is common and can have dire consequences in the elderly.³⁻⁵ In the United States, data has consistently found that the asthma emergency department (ED) visits and hospitalization rates for those above the age of 65 are higher than any other age group.⁶ Analysis of the National Asthma Survey has also demonstrated that both short-term measures of control (recent oral corticosteroid bursts or symptoms) and long-term measures (asthma attacks, urgent care visits, hospitalizations, and activity limitation in the previous year) were significantly worse in older adults with asthma.²

One theory of why asthma morbidity and mortality rates have remained unacceptably high among older adults is that the current diagnostic and therapeutic approaches do not address the unique challenges this age group faces. Some of these challenges include atypical asthma symptoms, inability to distinguish asthma from other medical conditions, use of complementary and alternative therapies, desire for independence in asthma management, and a lack of participation in asthma education.⁷ These, and other age-specific issues, are typically not addressed by physicians nor nurse educators. However, a theory-based educational intervention that is tailored to the individual goals and barriers may be well-suited to do so. Additionally, older adults may be more amenable to group-based interventions than younger cohorts.

The purpose of this study was to evaluate a self-regulation educational intervention, with both group and individual components, among a group of older adults with asthma.

Methods

Study Design

This study was a randomized controlled trial. Adult patients ≥ 55 years of age with persistent asthma were recruited from two large medical centers, in order to get a diverse representation of subjects. The first medical center was located in a predominantly, white, upper-middle class city (Ann Arbor, MI), whereas the second was located in an urban, predominantly African-American city with high rates of poverty (Detroit, MI). Persistent asthma was defined as the need for a controller medication every day for asthma, or the need for albuterol at least three times a week, in a patient with physician-diagnosed asthma. Demonstration of airway reversibility or airway hyper-reactivity was not be required, as current NIH NAEPP guidelines specifically state that “chronic asthma may be associated with a loss of response to bronchodilators”,⁸ and this is especially true in those with long standing asthma such as the elderly.⁹ Exclusion criteria included current tobacco use or a greater than 10 pack-year smoking history; any other significant pulmonary disease including COPD; or significant cognitive impairment such that participation in the trial would not be possible. The trial was registered at clinicaltrials.gov (NCT01979055). Written informed consent was obtained from all subjects prior to enrollment, and full IRB approval was granted.

At baseline, demographic information was collected. This included age, age of asthma diagnosis, race, and body mass index (BMI). Asthma information collected included asthma exacerbations over the past year (specifically hospitalizations, emergency department visits, or unscheduled office visits for asthma), oral corticosteroid use in the past year, asthma control as measured by the Asthma Control Test (ACT), and asthma quality of life as measured by the mini-Asthma Quality of Life Questionnaire (AQLQ). Asthma severity was based on asthma medication use and followed the NIH EPR-3 step therapy (1 = albuterol alone, 2 = low dose ICS, 3 = medium dose ICS or low dose ICS + LABA, 4 = medium dose ICS + LABA, 5 = high dose ICS + LABA, 6 = high dose ICS + LABA and biologic therapy or chronic oral steroids). Baseline objective measurements included the fraction of

exhaled nitric oxide (FENO) levels, spirometric values, and determination of atopic sensitization by skin prick testing to eight common allergens. Asthma medication adherence was based on response to the question “How often do you take your asthma medications as prescribed by your physician?”, with scores of 1-4 corresponding to responses ‘Not at all’, ‘Some of the time’, ‘Most of the time’, and ‘All of the time’. Finally, as the intervention was predicated upon the principles of self-regulation, asthma self-management/self-efficacy scores were measured using the Perceived Control of Asthma Questionnaire (PCAQ). The PCAQ is a validated 11-item questionnaire that has been used in asthma research.¹⁰

Randomization

Centralized randomization was performed by a data manager, and subjects were stratified by site. Subjects underwent block randomization with a block size of 6. The data manager had no contact with the participants.

Trial Intervention

Following enrollment, participants randomized into the intervention group were separated into cohorts of approximately 7 individuals, and completed a six-week asthma intervention based on the social cognitive theory of behavioral change. The intervention consisted of 3 in-person group sessions along with 3 one-on-one telephone sessions. Group sessions were comprised of 7 participants along with a health educator who served as the leader. All group and telephone sessions were conducted by a health educator who had received a two-day training session on the principles of self-regulation as well as the basics of asthma management.

The personalized intervention followed a self-regulation process in which the participant first selected a specific asthma-related problem they would like to address, observed and researched his/her

routine to see how asthma was preventing resolution of this problem, and finally identified and developed a plan to achieve this objective (Figure 1). Each step of the intervention was self-directed, with personalized assistance from the health educator. The final step of the intervention focused on teaching participants how to deal with asthma problems that may arise in the future. During the observation phase, participants were provided a peak flow meter and asked to monitor peak flow readings along with asthma symptoms over a two-week period, to determine factors that may negatively impact their asthma. A more detailed description of the intervention sessions can be found in the online repository. No specific medication changes were recommended by the study team.

Control group

Subjects randomized to the control group were provided a 30-minute asthma education session (which was also included in session 1 for the intervention group). Control group participants next were given a link to the American Academy of Allergy, Asthma and Immunology (AAAAI) patient asthma education website, available at <https://www.aaaai.org/conditions-and-treatments/asthma>. To provide attention-control matching, subjects in the control group were called on 3 occasions to ask if they had any questions regarding the website.

Outcomes

The primary outcome was severe asthma exacerbations, which were defined as the need for asthma hospitalizations, ED visits, or unscheduled urgent care visits. This outcome was assessed through interviews every 3 months, and the primary outcome was determined at 1 year. The primary outcome was assessed as both a dichotomous outcome as well as rate over time. The primary outcome was a composite of any component of the severe asthma exacerbations, and these outcomes were also assessed individually. Secondary outcomes that were assessed included the asthma control test (ACT) and mini Asthma Quality of Life Questionnaire (AQLQ). Additionally, lung function parameters were

obtained through use of spirometry (EasyOne Spirometer, mdd Medical Technologies, Andover, MD) and fraction of exhaled nitric oxide (NIOX FENO, Circassia Pharmaceuticals Inc, Morrisville, NC). Finally, as the intervention was predicated upon the principles of self-regulation, asthma self-management/self-efficacy scores were measured using the Perceived Control of Asthma Questionnaire (PCAQ). The PCAQ is a validated 6-item questionnaire that has been used in asthma research.¹¹

Statistical Methods

To compare the baseline characteristics between the two groups, a two sample t-test for the continuous variables, and Chi-square test for categorical variables, was performed. To compare the exacerbation rate between treatment groups at one year, a two-way contingency table assessing for the dichotomous outcome (any visits to hospital, ED and urgent care) between the intervention and control groups was constructed. A Chi-square test to examine for any association between exacerbations and predictor variables of interest was performed. Next, a linear mixed effect model was used to assess the associations of exacerbation rate and the treatment group longitudinally at four time points. The independent variables include time, treatment, and their interactions, and other baseline covariates adjusted were age, gender, duration of asthma, race, asthma medication severity score, and site. Besides the primary outcome, secondary outcomes examined included the ACT, AQLQ, and PCAQ scored. For each outcome, the model was fit for 172 subjects who had at least one intervention treatment in the treatment group per modified intent to treat analysis, as well as all 189 subjects per intent to treat analysis. SAS version 9.3 was used to perform all statistical analysis.

Sample size

The sample size calculation was based on our pilot study of 74 subjects.¹² A log-linear regression model was used to model the outcome of severe asthma exacerbations, using intervention group and baseline healthcare utilization count as covariates. The over-dispersion parameter was found to be

1.44. Therefore, with a two-sided type I error rate of 5%, a sample size of 306 subjects would provide 80% power to detect a significant difference in the rate of healthcare utilization between intervention and standard care groups, adjusted for differences in baseline covariates. During the course of the study, enrollment was found to be more challenging than expected. After an interim analysis of the primary endpoint, enrollment was eventually limited to 189 subjects.

Results

Between November 2013 and April 2016, a total of 289 eligible subjects who met inclusion and exclusion criteria were contacted. Of those, 100 declined to participate, leaving 189 participants who were initially randomized (94 to the intervention group, and 95 to the control group). Figure 1 demonstrates the flow of all subjects through protocol. Of those initially randomized to the intervention group, 17 declined further participation, did not receive a single intervention dose, and therefore were excluded from the modified intent to treat analysis. In the remaining 77 subjects allocated to the intervention arm, 40 (51.9%) completed all 6 intervention steps, while the remaining 37 completed at least one step. In the control group, 85 of the 95 (89.5%) subjects completed the entire protocol including follow-up at 1 year, whereas in the intervention group 60 of the 77 (77.9%) subjects completed the protocol including follow-up at 1 year.

Table 1 shows the baseline comparisons of subjects included in the modified intent to treat analysis. There was only one significant differences between the two groups, as those in the intervention group were minimally more compliant at baseline than those in the control group (3.7 vs 3.5, $p = 0.04$). The average age of subjects was 66 years, approximately 75% were female, and the average participant was obese with a BMI of 31.4. Approximately 60% of subjects would be considered atopic based on skin prick testing. When looking at baseline asthma characteristics, the average

duration of asthma was 32 years, with approximately half of subjects having late onset asthma (defined as asthma diagnosed after the age of 40). The average medication severity score was 3.4, indicating that patients would be 'moderate persistent' according to the NIH guidelines. Asthma morbidity was evident at baseline, as 44% of all subjects had suffered an asthma exacerbation requiring hospitalization, ED visit, or urgent care visit in the previous year. Additionally, the Asthma Control Test (ACT) score was in the uncontrolled range at 17.7. The baseline FEV1 percent predicted was decreased at 70.9%, and after bronchodilator therapy this improved to 75.8%. Importantly, even after bronchodilator therapy 30% of subjects did not have a FEV1/FVC ratio of greater than 70%, and would be classified as fixed airway obstruction (FAO). A comparison including the 17 subjects excluded at baseline (full intent to treat population) showed similar results (online repository, eTable 1).

When examining the primary outcome (severe asthma exacerbations at one year), subjects in the intervention arm were significantly less likely to suffer an exacerbation than those in the control arm (26.9% vs 47.2%, $p = 0.007$). Breaking down the individual components, there was a significant decrease in ED visits and unscheduled visits, but not hospitalizations (Figure 2). The asthma exacerbation rate was also significantly lower in the intervention compared to the control group (0.8 vs 1.9, $p = 0.020$). To control for confounding, a mixed effects model was constructed. After controlling for confounding variables, the time by group intervention variable remained significant, and the odds ratio of an asthma exacerbation at 12 months in the intervention group was 0.28 as compared to the control group ($p = 0.021$).

As shown in Table 2, when examining secondary outcomes, there was a trend towards improvement in the ACT score, though this did not reach significance (19.9 vs 18.6, $p = 0.08$). Self-management scores were improved in the intervention group (8.9 vs 8.4, $p = 0.04$). AQLQ scores were not significantly different between the groups, nor was there any difference in medication adherence.

No change was noted in spirometric values nor in FENO levels. Figure 3 shows the severe asthma exacerbation rate, which was significantly lower in the treatment group ($p = 0.046$).

When looking at all subjects (intent to treat analysis) including the 17 excluded who did not receive at least one intervention treatment, similar results were found. As shown in the online supplementary table 2, asthma exacerbations (and specifically ED visits and unscheduled visits), asthma exacerbation rates, and self-management scores were all significantly improved in the intervention group compared to the control group. Asthma exacerbations remained significantly decreased after analysis by the mixed effects model ($p = 0.041$).

Discussion

In this randomized controlled trial, we found that a self-regulation educational intervention was effective in decreasing severe asthma exacerbations among older adults over a one-year period. The intervention was not based on medication adjustments or changes, and observed improvements were likely based on greater asthma self-management skills. Although there were challenges in getting subjects to complete all phases of the intervention, in both the intent-to-treat and modified intent-to-treat analysis, positive results were demonstrated.

The intervention used in this study was based on the behavioral theory of self-regulation. Previous research on asthma educational strategies often reveals that those developed with a behavioral underpinning are most effective. We intentionally chose a self-regulation behavioral theory for this intervention, as it lets participant choose asthma problems and goals most relevant to their situation. In this way, the older adults were more invested than they may have been with traditional asthma education. As the current national asthma guidelines have minimal content specifically tailored

towards issues that may affect older adults, our intervention allowed participants to address goals that were directly applicable and germane.

In fact, both self-management scores and quality of life improved with the intervention ($p = 0.04$ and $p = 0.08$, respectively), whereas spirometric measurements and FENO readings did not. More importantly, by increasing the self-efficacy a participant possesses, the exacerbation rate was decreased. Older adults with asthma are more likely to have fixed airway obstruction compared to younger populations, and therefore focusing on improvement in FEV1 may be counterproductive. Of note, other trials in older adults that have found decreased exacerbation rates do not always show meaningful changes in lung function parameters.^{13,14}

The intervention was specifically designed to have individual components as well as group interaction. Group sessions have been found to be effective for older adults in a number of interventions and conditions, such as diabetes and osteoarthritis.^{15,16} The camaraderie and shared experience sessions may be especially appealing to older adults, who are more likely than other age groups to suffer from social isolation. However, there were challenges to getting all participants to all sessions, including transportation and care giver roles. Whether novel approaches such as telehealth can overcome some of these barriers while maintaining the integrity of the intervention remains to be further explored. In different trials, the total number of sessions for asthma education ranges from one to more than ten,^{14,17-19} and it is possible that the number of sessions for older adults needs to be lower than the current protocol. Additionally, a trial for older adults with asthma using a self-management support intervention with a flexible number of sessions was found to be successful in improving asthma control, quality of life, and ED visits.¹⁴ In this trial, asthma care coaches delivered the intervention at home or in the primary care clinic. Further exploration of end-user preferences and the most cost-effective behavioral interventions is needed.

There were limitations of the intervention. Participants were not blinded (though outcome assessors were) and this may have introduced bias. Nearly 20% who were randomized to the intervention group declined to participate once they learned more details of the number of sessions and phone calls. The target enrollment goal was not achieved, though a positive outcome was demonstrated even without reaching this goal. Additionally, the percent of subjects lost to follow-up in the intervention group was higher in the control group, which may indicate that the frequency or amount of the intervention was excessive.

In conclusion, a self-regulation intervention that combined group support and individual telephone phone calls was effective in decreasing asthma exacerbations among older adults over a 1-year period. There were challenges in enrolling and retaining subjects, and these need to be further addressed. However, both a modified intent to treat analysis, and a full intent to treat analysis, did show this method can be effective for older adults.

Figure legends

Figure 1 – Consort flow diagram

Figure 2 – Asthma exacerbations by type (Hospitalizations, ED visits, and unscheduled office visits)

Figure 3 - Mean exacerbation rate over 12 months. Those in the intervention group had a significantly lower rate than the control group in a linear mixed effects model ($p = 0.046$).

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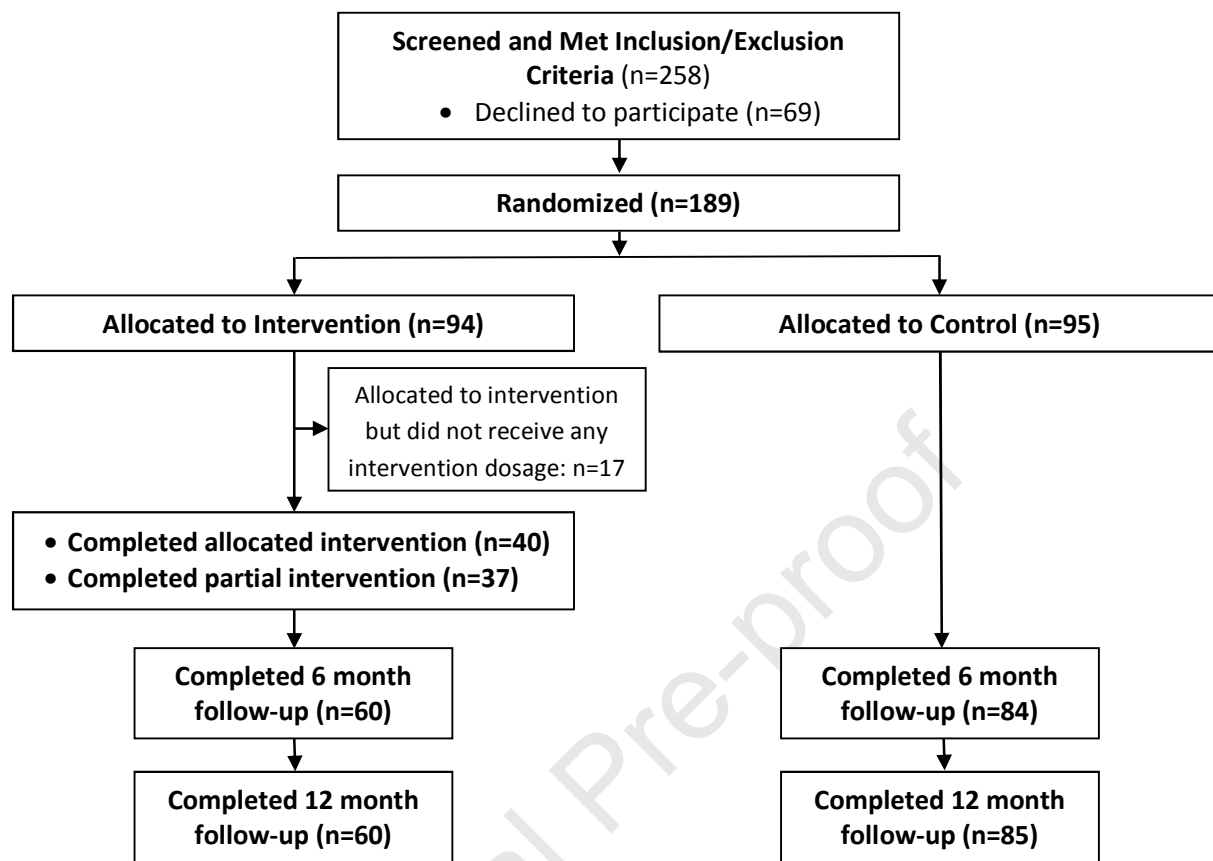
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Table 1 – Baseline values of subjects in the modified intent-to-treat protocol

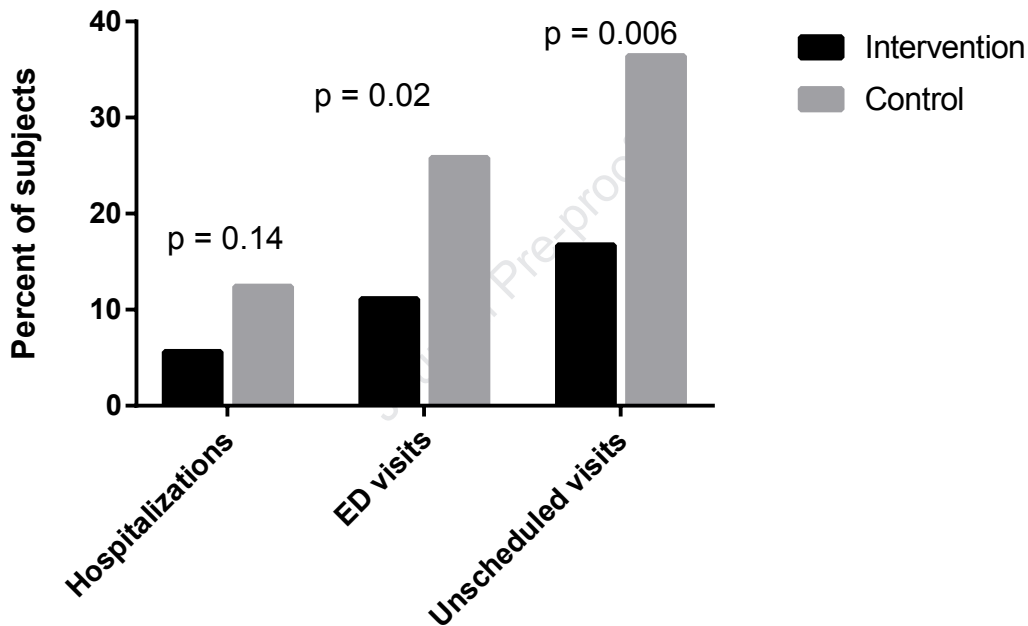
	Total Cohort	Control	Intervention	<i>P</i> Value
Number of subjects	172	95	77	
Male gender, n (%)	42(24.4)	26(27.4)	16(20.8)	0.32
Age of enrollment, years	66.0(7.3)	66.0(7.5)	65.9(7.1)	0.90
Asthma duration, years	32.4(21.1)	32.3(21.4)	32.4(20.7)	0.97
Race, White, n (%)	113(65.7)	65(68.4)	48(62.3)	0.64
Black, n (%)	54(31.4)	27(28.4)	27(35.1)	
Other, n (%)	5(2.9)	3(3.2)	2(2.6)	
Tobacco Pack Years	2.5(5.6)	2.7(6.3)	2.1(4.6)	0.45
Body mass index (BMI)	31.4(7.3)	30.7(7.3)	32.3(7.3)	0.17
NIH severity score ³	3.5(1.2)	3.6(1.1)	3.5(1.3)	0.41
Asthma Exacerbations, (%)	76(44.2)	41(43.2)	35(45.5)	0.76
Hospitalization	18(10.5)	11(11.7)	7(9.1)	0.58
Emergency visit	30(17.4)	17(17.9)	13(16.9)	0.86
Unscheduled visit	59(34.5)	31(32.6)	28(36.8)	0.56
Oral corticosteroid use in past year, n (%)	80(47.6)	40(42.6)	40(54.1)	0.14
FeNO	28.8(26.4)	29.3(25.5)	28.2(27.5)	0.79
Atopic Sensitization, n (%)	104 (60.5)	59(62.1)	45(58.4)	0.63
FEV1/FVC ratio, pre-treatment %	93.7(13.7)	92.9(13.9)	94.7(13.6)	0.41
FEV1/FVC ratio, post-treatment %	95.6(15.6)	94.6(17.1)	96.8(13.5)	0.36
FEV1 Pre-treatment % Predicted	70.9(20.9)	71.2(21.3)	70.6(20.6)	0.84
FEV1 Post-treatment % Predicted	75.8(19.7)	76.2(19.8)	75.2(19.6)	0.75
Asthma control test	17.7(4.6)	17.7(4.6)	17.7(4.7)	0.99
Asthma quality of life	5.2(1.2)	5.1(1.2)	5.2(1.2)	0.74
Medication adherence	3.6(0.7)	3.5(0.7)	3.7(0.6)	0.04
Self-management score	8.0(1.9)	7.9(2.0)	8.1(1.8)	0.41

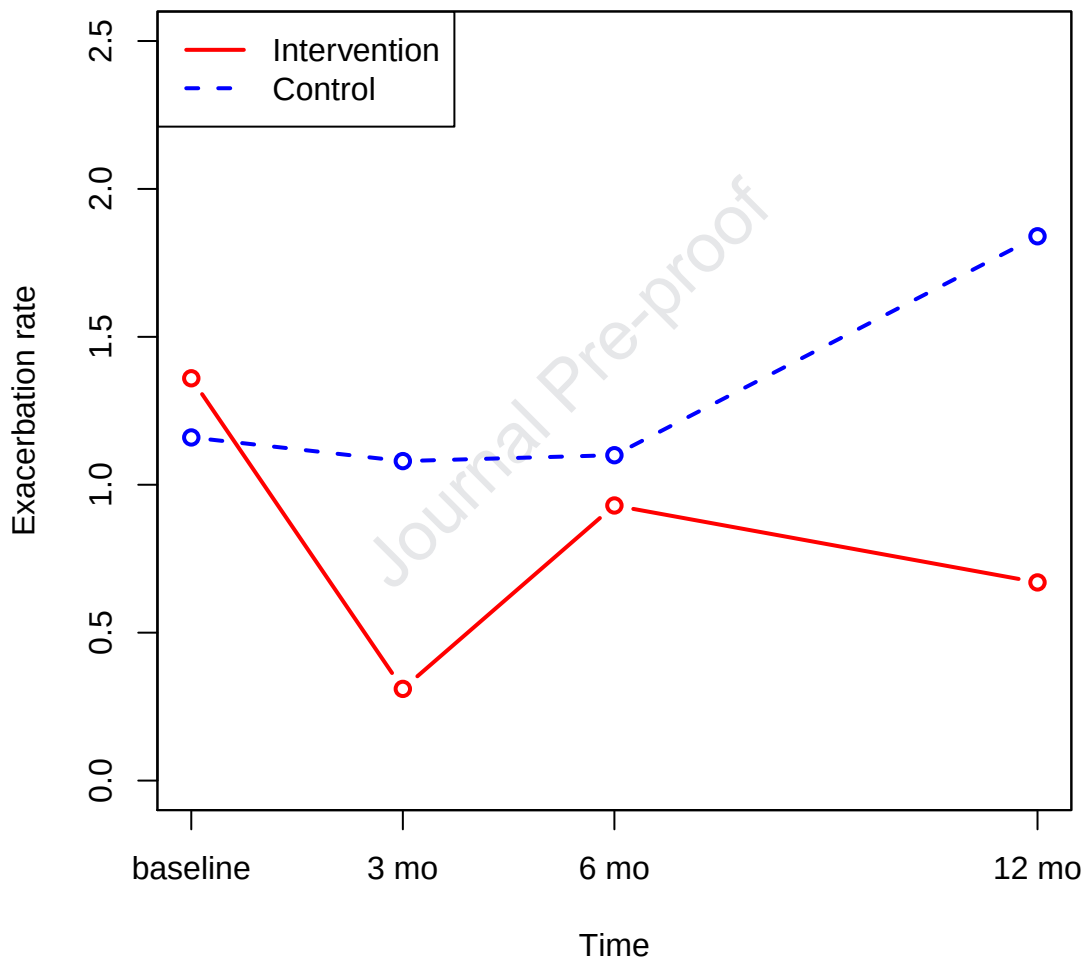
Table 2 – Outcomes of subjects

	Total Cohort	Control	Intervention	<i>P</i> Value
Number of subjects	156	89	67	
Depression, n (%)	5.2(8)	6.7(6)	3.1(2)	0.32
Asthma Exacerbations, (%)	38.5(60)	47.2(42)	26.9(18)	0.01*
Hospitalization	9.6(15)	12.4(11)	6.0(4)	0.18
Emergency visit	19.2(30)	25.8(23)	10.5(7)	0.02*
Unscheduled visit	28.4(44)	36.4(32)	17.9(12)	0.01*
Oral corticosteroid use in past year, n (%)	37.2(58)	41.6(37)	31.3(21)	0.19
Asthma Exacerbations rate	1.4(3.0)	1.9(3.6)	0.8(1.9)	0.02*
Hospitalization	0.3(1.0)	0.3(1.1)	0.2(0.9)	0.35
Emergency visit	0.4(1.1)	0.6(1.3)	0.2(0.8)	0.02*
Unscheduled visit	0.7(1.6)	0.9(1.8)	0.4(1.1)	0.03*
General Health	26.0(7.8)	25.6(7.5)	26.5(8.2)	0.49
FeNo	27.8(23.4)	29.3(24.1)	25.6(19.4)	0.39
FEV1, pre-treatment value	1.8(0.6)	1.8(0.7)	1.7(0.6)	0.35
FEV1 Pre-treatment % Predicted	72.6(19.9)	72.1(20.3)	73.3(19.6)	0.75
FEV1/FVC ratio, pre-treatment % predicted	96.3(12.9)	96.0(14.0)	96.6(11.4)	0.81
Asthma control test	19.1(4.4)	18.6(4.7)	19.9(3.9)	0.08
Asthma quality of life	5.5(1.1)	5.5(1.2)	5.6(1.0)	0.39
Medication adherence	3.6(0.7)	3.5(0.7)	3.6(0.6)	0.46
Self-management	8.6(1.5)	8.4(1.7)	8.9(1.2)	0.04*
API overall	42.3(5.4)	41.9(5.5)	42.8(5.3)	0.28



Asthma exacerbations





eTable 1 - Baseline characteristics of all subjects, intent to treat protocol

	Total Cohort	Control	Intervention	<i>P</i> Value
Number of subjects	189	95	94	
Male gender, n (%)	49(25.9)	26(27.4)	23(24.5)	0.65
Age of enrollment, years	66.0(7.3)	66.0(7.5)	65.9(7.2)	0.93
Asthma duration, years	32.1(20.9)	32.3(21.4)	31.8(20.4)	0.87
Race, White, n (%)	123(65.1)	65(68.4)	58(61.7)	0.61
Black, n (%)	60(31.8)	27(28.4)	33(35.1)	
Other, n (%)	6(3.2)	3(3.2)	3(3.2)	
Body mass index (BMI)	31.1(7.2)	30.7(7.3)	31.6(7.2)	0.42
NIH severity score	3.5(1.2)	3.6(1.1)	3.5(1.3)	0.39
Asthma Exacerbations, (%)	81(42.9)	41(43.2)	40(42.6)	0.93
Hospitalization	20(10.6)	11(11.7)	9(9.6)	0.64
Emergency visit	32(16.9)	17(17.9)	15(16.0)	0.72
Unscheduled visit	63(33.7)	31(32.6)	32(34.8)	0.76
FeNO	28.6(25.5)	29.3(25.5)	27.9(25.7)	0.72
Atopic Sensitization, n (%)	116(61.4)	59(62.1)	57(60.6)	0.84
FEV1/FVC ratio, pre-treatment %	93.4(13.6)	92.9(13.9)	93.8(13.4)	0.65
FEV1/FVC ratio, post-treatment %	95.6(15.3)	94.6(17.1)	96.7(13.3)	0.36
FEV1 Pre-treatment % Predicted	70.5(20.6)	71.2(21.3)	69.9(19.9)	0.66
FEV1 Post-treatment % Predicted	75.5(19.2)	76.2(19.8)	74.9(18.6)	0.64
Asthma control test	17.6(4.6)	17.7(4.6)	17.6(4.6)	0.78
Asthma quality of life	5.1(1.2)	5.1(1.2)	5.1(1.2)	0.95
<u>Medication adherence</u>	<u>3.5(0.7)</u>	<u>3.5(0.7)</u>	<u>3.6(0.7)</u>	<u>0.09</u>
Self management	8.0(1.9)	7.9(2.0)	8.1(1.8)	0.35

eTable 2 – Outcomes of all participants (intent-to-treat analysis)

	Total Cohort	Control	Intervention	P Value
Number of subjects	161	89	72	
Depression, n (%)	5.7(9)	6.7(6)	4.4(3)	0.53
Asthma Exacerbations, (%)	67.9(61)	47.2(42)	26.4(19)	0.007*
Hospitalization	9.3(15)	12.4(11)	5.6(4)	0.14
Emergency visit	19.3(31)	25.8(23)	11.1(8)	0.02*
Unscheduled visit	27.5(44)	36.4(32)	16.7(12)	0.006*
Oral corticosteroid use in past year, n (%)	36.7(59)	41.6(37)	30.6(22)	0.15
Asthma Exacerbations rate	1.4(3.0)	1.9(3.6)	0.8(1.9)	0.02*
Hospitalization	0.3(1.0)	0.3(1.1)	0.2(0.9)	0.28
Emergency visit	0.5(1.2)	0.6(1.3)	0.3(0.9)	0.03*
Unscheduled visit	0.7(1.5)	0.9(1.8)	0.4(1.0)	0.02*
General Health	26.1(8.0)	25.6(7.5)	26.8(8.7)	0.39
FeNo	27.6(23.4)	29.3(24.1)	25.3(22.4)	0.34
FEV1, pre-treatment value	1.8(0.6)	1.8(0.7)	1.7(0.6)	0.32
FEV1 Pre-treatment % Predicted	72.6(19.8)	72.1(20.3)	73.3(19.4)	0.75
FEV1/FVC ratio, pre-treatment % predicted	96.3(12.9)	96.0(14.0)	96.6(11.3)	0.80
Asthma control test	19.1(4.5)	18.6(4.7)	19.7(4.1)	0.11
Asthma quality of life	5.5(1.2)	5.5(1.2)	5.6(1.1)	0.49
<u>Medication adherence</u> <u>Compliance</u>	3.6(0.7)	3.5(0.8)	3.7(0.6)	0.32
Self-management	8.7(1.5)	8.4(1.7)	8.9(1.1)	0.03*
API overall	42.2(5.4)	41.9(5.5)	42.7(5.3)	0.36

Description of the self-regulation intervention

The figure below lists an overview of the design of the self-regulation intervention.



The program uses an adaption of Zimmerman's assessment of developmental phase of patients in relation to self-regulation.^{1,2}

Session #1 – Problem Selection and Routine Research

Session #1 is conducted as a group session of 7 participants, and is led by a health educator. The sessions were held at a community center location central to participants.

The first step for each participant is to choose an area that causes problems or frustration related to asthma management. We provided a list of approximately 15 problems frequently experienced by older adult patients. These problem choices will be from our research on older adults,^{3,4} literature review on factors associated with poor asthma control, as well as information from previous focus groups.⁵ If a patient had a problem not included in the list, that was acceptable as well. The goal of this step is to identify problems as seen from a patient's viewpoint, not necessarily from a health care provider's perspective. A sample of possible problems is listed in eTable 3.

eTable 3 – Sample problem selection

I wheeze or have symptoms when I exercise or do physical activity

I'm not sure I really have asthma. Could it be something else?

I do not feel independent in my care for my asthma. It is difficult for me to rely on my family members and friends for help with my asthma care

I have necessary tasks and activities that expose me to asthma triggers and make my symptoms worse

Next, participants were instructed on methods to observe and research their activity over 10 days. This will be done using a diary and peak flow meter. Each day, participants tracked their peak flow values, asthma symptoms, and observed any barriers that negatively affect their asthma control.

Each participant was asked to observe potential social, physical, and culture-related associations between asthma symptoms, allergy symptoms, and levels of physical activity. Particular attention was related to barrier interference of optimal asthma control. Participants were provided potential lists of barriers. An abbreviated list of possible barriers is presented in eTable 4.

eTable 4 – Sample barrier selection

I'm not sure of what triggers my asthma	My asthma is unpredictable – I never know when it will flare up
I feel sad or depressed, and wonder if this is making my asthma worse	I can't afford my medications or to see my

	doctor
It is hard for me to do physical activity, so I cannot try to make my lungs stronger to help control my asthma	I do not know who to call if I am having an asthma attack

Session #2 – Identification of self-management goal and Discussion of Rewards

As with the first session, Session #2 was conducted as a group session, and was held 2 weeks after Session #1. Participants first discussed their progress since Session #1, including their ability to identify a problem and recognize potential barriers. Next, the health educator assisted participants as they identify an asthma self-management goal. The goal was often based on the barriers and problems identified during the self-observation period. Short-term and long-term goals were both explored, and the health educator helped the participants break each goal down into manageable components.

The health educator also introduced the concept of developing a plan to achieve the short term goal. This involved the participants identifying barriers or other reasons that prevent them from reaching their goal, and thinking of strategies to overcome these barriers. A key principle of self-regulation is that participants themselves formulate the eventual plan of overcoming obstacles, though the health educator is available for assistance and to help the participant assess feasibility.

Sessions #3,4,5 – Tailored problem solving and self-regulation, asthma action plan generation, additional asthma education

In contrast to the first two sessions, Sessions #3-5 were conducted over the telephone during weeks 3 - 5. During these sessions, the health educator called each participant to discuss challenges encountered and progress made towards self-management goals. The health educator also discussed the possibility of altered plans if appropriate, and discussed effective ways to communicate with physicians. In addition, issues of independence in asthma management and asthma symptom discrimination (key concepts from our qualitative work with older adults with asthma)⁵ were further explored.

Session #6 – Tying it all together and plans for the future

Session #6 was conducted in person again. Participants had a chance to share with the group their level of progress and goal attainment. The ability to apply the self-regulation process to other asthma problems, as well as to other health conditions, was explored. Myths, stereotypes, and characteristics of successful aging were addressed, along with areas of personal growth and accomplishment through the program.

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