Allergen-Impermeable Bed Covers for Adults with Moderate to Severe Asthma and Dust Mite Allergy

Judy Nam

A. Study Purpose and Rationale

The number of persons in the United States reported to have asthma doubled between 1980 and 1996, then reached a plateau (Manino, 2002). In 2001, the Center for Disease control estimated that 20.3 million people had asthma (CDC, 2001). Asthma remains a growing concern in this country, particularly in inner-city African-American and Latino populations. While the management of asthma has improved over the past two decades, these inner-city populations showed increased rates of morbidity and mortality from asthma. African-Americans and Hispanic Americans are two to six times more likely to die from asthma than whites (Lenoir, 1999). In addition to socioeconomic issues and access to healthcare, there have been many theories put forward to explain this finding. Current theories include: exposures to allergens, pollutants and infections.

Exposure of asthma patients to irritants or allergens to which they are sensitive has been shown to increase asthma symptoms and precipitate asthma exacerbations (Cockcroft, 1979). The National Asthma Education and Prevention Program recommends that those patients with persistent asthma on daily medications should be assessed for exposure and allergy to indoor perennial allergens, such as dust mite (1997). For patients with persistent asthma found to have dust mite sensitization, this panel of experts sites allergen avoidance as the most important step in the treatment. Because the bed is the most important source of dust mite exposure (Platts-Mills, 1982), the current strongest recommedations to control dust mite exposure are: encasing mattresses and bedding in an allergen-impermeable covers, and to wash bedding in hot water weekly.

Although many studies have documented a decrease in mite allergen 6 or more months following a range of interventions, it remains unclear if allergen avoidance results in a clinical benefit (Woodcock, et al., 2003; Cloosterman, et al., 1999). It has been a challenge to establish whether effective allergen avoidance can be achieved through measures that are practical and cost effective and flexible enough to suit individual needs, and to determine which patients may benefit from such interventions.

This study will address whether dust mite allergen avoidance through allergen-impermeable mattress covers and bedding covers will have a clinical benefit on patients with persistent asthma and dust mite allergy.

B. Study Design and Statistical Analysis

a. Study Arms

All eligible subjects will proceed in a 4 week run-in phase, during which they will complete a diary card documenting beta₂-agonist use, morning peak expiratory flow rate (record the best-of-3 efforts [Mini-Wright flowmeter, Clement Clarke International], scores for daytime and nighttime symptoms. Those who complete the diary cards for at least 14 days will undergo stratification as moderate or severe persistent asthma by this information, then randomly assigned to receive allergen-impermeable or placebo bedding. At randomization, they will undergo complete detailed questionnaire regarding demographics, medication use, smoking exposure, time spent away from home, occupational exposures. They will also be administered the St. George Hospital Respiratory Questionnaire to assess quality of life.

The active intervention arm and the placebo arm will be asked to keep covers on their beds and bedding for one year.

b. Number of subjects to be enrolled / Methods of Statistcal Analysis

Number of subjects to be enrolled in each arm = 191 subjects

This was determined by the unpaired t-test, using:

- mean of the placebo arm (frequency of beta₂-agonist use) as 4 puffs/day
- mean of the active intervention arm as 3 puffs/day
- standard deviation = 3 puffs/day
- effect = 1 puff/day
- alpha = 0.05
- power = 0.90

c. Randomization

Patients will be stratified as moderate or severe asthmatic prior to randomization to achieve equal numbers of each in both arms.

C. Study Procedure

There will be a 2 year enrollment period. Each subject will participate for one year plus a one month run-in period.

a. Allergy testing

According to the National Asthma Education and Prevention Program, the patients eligible to participate in this study have indications for allergy testing. Skin prick testing will be performed once at the beginning of the study. This test is slightly uncomfortable, but is usually well tolerated and accurate, even in small children and infants. Local itch and swelling normally subsides within 1-2 hours. More prolonged or severe swelling may be treated with an oral antihistamine, topical corticosteroid cream and an ice pack. Occasional patients will experience feel dizzy or light-headed and need to lie down. Severe allergic reactions from allergy testing in asthma are very rare, and can be avoided by not testing patients during an asthma exacerbation. An allergist will administer the test and observe the patient for 1 hour after the procedure for any adverse reactions.

b. Dust Collection

The patient's home will be visited to collect dust at the beginning of the study, at 6 months, and at 12 months. Dust mite allergen on the patient's bed will be collected by vacuuming of a 1 m^2 area of the mattress for 2 minutes through a filter device. The samples will be assayed by monoclonal enzyme-linked immunosorbent assay for dust mite allergen, Der p 1 (Indoor Biotechnologies) (microgram allergen/gram of dust).

Patients will be asked to record the best of 3 Peak Expiratory Flow Rate (PEFR) daily for a total of 12 weeks through the year (increments of 4 weeks at a time). Patients will each be given a peak expiratory flow meter, a small hand-held device with a mouthpiece at one end and a scale with a moveable indicator (usually a small plastic arrow). Asthmatic patients will be familiar with the method, but will be instructed to proper use of the device. (They will be instructed to breathe in as deeply as possible, then blow into the instrument's mouthpiece as hard and fast as possible.)

D. Study Drug

N/A

E. Medical Device

Allergen-impermeable microfiber covers (Allergy Control Products) is a commercially available device which retain >99.5% of 0.4micrometer particles. (Dust mite allergens are about 10 micrometer particles.) The sham covers will be of the same material but of a conventional weave allowing 85% of

allergen to pass through. The patients will be asked to use the covers on their beds, pillows, blankets or duvets for the duration of the study, one year.

F. Study Questionnaires

Patients will be assessed with questionnaire, a 4-week diary of symptoms (see attached.) and 4-diary of daily morning best-of-3 peak expiratory flow rates. These evaluations will occur at the beginning of the study, at 6 months, and at 12 months. They will also be asked about the number of emergency department visits and unscheduled physician visits for asthma exacerbations, as well as frequency of systems steroid use in the previous 6 months period. Patients will receive a reminder phone call at months 5 and 11 to commence with the 4-week diary.

G. Study Subjects

a. Inclusion Criteria

- moderate persistent or severe persistent asthma *
- positive skin test to dust mite (at 15 minutes, wheal equal to or greater than positive control, histamine)
- ages 18-50 yrs
- resident of upper Manhattan
- The National Asthma Education and Prevention Program defines:

| Moderate Persistent Asthma as | | | | | |
|-------------------------------|--|--|--|--|--|
| symptom: | daily symptoms | | | | |
| | daily use of inhaled short-acting beta ₂ -agonist | | | | |
| | exacerbations affect activity | | | | |
| | exacerbations ≥ 2/week, may last days | | | | |
| nighttime symptoms: | >1/week | | | | |
| lung function: | FEV1 or PEFR>60% to <80% predicted | | | | |
| Severe Persistent Asthma as | | | | | |
| symptoms: | Continual symptoms | | | | |
| | Limited physical activity | | | | |
| | Frequent exacerbations | | | | |

FEV1 or PEFR \leq 60% predicted

Frequent

b. Exclusion Criteria

nighttime symptoms:

lung function:

chronic systemic steroid use

- underlying chronic lung disease other than asthma
- current allergen-impermeable bed cover use
- diagnosis of CHF
- pet owner and sensitization to their pet by skin test
- pregnant
- more than one bed in the bedroom

This study is not restricted by race or gender.

No vulnerable populations will be included in this study.

H. Recruitment of Subjects

Physicians practicing in Pulmonary, Allergy, General Medicine, Asthma clinics in upper Manhattan will given stud description and will agree that the patient is suitable for the study. The patient's physician will ascertain if the patient is willing to discuss the study with the research team. Patients will be invited by phone call to discuss the study. After obtaining consent, those who qualify will be seen by an allergist who will administer the allergy skin prick test to dust mite. Those with a dog and/or cat with also be skin tested to dog and/or cat. Those found to have sensitization to dust mite allergen and not sensitized to their pet will commence with the study.

I. Confidentiality of Study Data

After randomization, the patient's initials, date of birth, and measurements for his/her bed/bedding will be sent to the ICCR. Each patient will be assigned a research number. The bedding measurements will be sent by the ICCR to the manufacturer of the covers who will mail the boxes to the research center with only the research number as an identifier.

Data will be stored so that only researchers can access the information.

J. Potential Conflict of Interest

Neither the investigators nor the University has any propriety interest in the study device.

K. Location of Study

The intervention or placebo will take place in patients' homes in upper Manhattan. The intervention does not involve risk to the subjects.

Allergy testing and interviewing will take place at ICCR.

L. Potential Risks

The intervention, allergen-impermeable cover, is well tolerated. Previously studies utilizing these products have not reported any adverse reaction or worsening of asthma.

M. Potential Benefits

Patients may have improved asthma symptoms and quality of life.

N. Alternative Therapies

The proposed intervention is not experimental. Allergen impermeable covers are recommended by The National Asthma Education and Prevention Program and are currently routinely prescribed by physicians taking care of dust-mite allergen sensitized patients.

O. Compensation to Subjects

Patients will be compensated for any expenses incurred while traveling to and from CUMC. At the end of the study, all subjects in the placebo arm will receive allergen-impermeable covers for their beds.

P. Cost to Subjects

None.

Q. Minors as Research Subjects.

N/A

R. Radiation or Radioactive Substances

N/A

S. References

CDC, National Center for Health Statistics. Asthma prevalence, health care use and mortality, 2000-2001.

Cockcroft DW, et al. Determinants of allergen-induced asthma: dose of allergen, circulating IgE antibody concentration, and bronchial responsiveness to inhaled histamine. Am Rev Respir Dis, 1979 Nov;120(5):1053-8.

Cloosterman SGM, Shermer TRJ, et al. Effects of house dust mite avoidance measures on Der p 1 concentrations and clinical condition of mild adult house dust mite-allergic asthmatic patients, using no inhaled steroids. Clin Exp Allergy, 1999;29:1336-1346.

Lenoir MA. Asthma in inner cities .J Natl Med Assoc.1999 Aug;91(8 Suppl):1S-8S.

Mannino DM, Homa DM, Akinbami LJ, et al. Surveillance for asthma---United States, 1980--1999. In: CDC surveillance summaries (March 29). MMWR 2002;51(No. SS-1).

National Asthma Education and Prevention Program Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma, NIH Publication No. 97-4051, 1997.

Platts-Mills TAE, Tovey ER, Mitchell EB, et al. Reduction of bronchial hyperreactivity during prolonged allergen avoidance. Lancet 1982;2:675-8).

Woodcock, A, Forster, L, Matthew, E, et al. Control of exposure to mite allergen and allergen-impermeable bed covers for adults with asthma. N Engl J med 2003;349:225-236.

| Bar IT, Schumscher GE, Freeman S, Lebhone M, Baku AW, Jooes PW. American Transform, Modification, and Vididation of the 3t. George's Respiratory Quotinomates: Clinical Therapositics 2000; 22:1121-1161. | | | | | | less than a day | · |
|--|--|--|--|--|--|--|---|
| Comment Comment (Included Service Comment) | | | | | 7) Over the last 4 weeks, in an average week, how many good | pone | 0 |
| T. C. C | h 1 m | | | | days (with few lung/respiratory problems) have you had? | 1 or 2 | 0 |
| The St. George's Hospital Respiratory Questionnaire This questionnaire is designed to help us learn more about how your breathing is troubling you | | | | ubling you | | 3 or 4 nearly every day | 0 |
| and how it affects your life. We are using it to find out which aspects of your illness cause you the most | | | | | | every day | 0 |
| problems, rather than what the doctors and nurses think your problems are. Please read the instructions carefully and ask if you do not understand anything. Do not spend a long time deciding on your | | | | | 8) If you wheeze, is it worse in the morning? | No | 0 |
| answers. | years, Louisia | Actual Conf. Co. | a occording on | NAE | If you don't wheeze, go to the next page. | Yes | 0 |
| PART 1 - | our Week Desc | ription | | | | | |
| Please describe how often your lang/respira | ory problems have | | over the last fo | M. | Section 1: | | |
| weeks. Please fill in one circle for each question. | | | | | How would you describe your lung trapiratory condition? Please The most important problem I have | e fill in one circle only. | |
| | most several very days | a few | only with | not | Causes me a ior of problems Causes me a few problems | | |
| | day a week | a month | infections | all all | Causes me no problem | | |
| 1) Over the last 4 weeks, I have coughed | 0 0 | 0 | 0 | 0 | If you have ever held a job, please fill in one of the circles. | | |
| 2) Over the 4 weeks, I have brought | 0 0 | 0 | 0 | 0 | My lung/respiratory problem made me stop my job My lung/respiratory problem interferes with my job or m | ade me change my job | 0 |
| up phlegm (spanam) | | | | | My lung/respiratory problem does not affect my job | | |
| | 0 0 | o | 0 | 0 | Section 2: These are questions about what activities usuals Please fill in each circle that applies to you now. | | |
| shortness of breath | | | | | Sitting or lying still | | |
| Over the last 4 weeks, I have had episodes of wheezing | 0 0 | 0 | 0 | 0 | Washing yourself or dressing. Wasking in the house | | |
| | | | | | Walking outside on level ground. | | |
| During the last 4 weeks, how many sever episodes of lung/respiratory problems har | | nt more to 3 epise | than 3 episode odes | 0 | Walking up a flight of stairs | | 0 |
| | 0.0000000 | 2 epist | odes | 0 | Playing sports or active games (baseball, tennis, etc) | 0 | 0 |
| | | I epise No epi | isodes | 0 | Section 3: These are more questions about your cough and Please fill in each circle that applies to you now. | | |
| 6) How long did the worst episode of lung's | emintory | a week | k or more | . 0 | Coughing hurts | In C | M. E |
| problem last? Go to Question 7 if you didn't have a sex | | 3 or m | ore days days | | Coughing makes me tired | | . (|
| | | | | | | | |
| | | | | | | | |
| I am abort of besath when I bend o | ver . | | | 0.0 | My breathing problem makes is difficult to do driven a col- | | |
| I am short of breash when I bend on My coughing or breasing attacks. Decome photostef and | ver | | - (| 0 0 | My breathing problem makes it difficult to do things such very heavy manual labor, refung a bala, neurong, swerming | g fast, | |
| My coughing or breathing disturbs I become exhausted easily | my sleep | | 6 | 0 0 | My breathing problem makes it difficult to do things such very henry massal labor, refeng a blae, navane, awirming or playing competitive sports | g fast, | |
| My coughing or breathing disturbs | ny sleep | our lung/resp | (otrusury probi | 0 0 0 0 em may | very heavy manual labor, riding a bile, naming, swirming or playing competitive sports. Section 7. We would like to know how your breathing usus | g fast, O | |
| My coughing or breathing disturbs. I become exhausted easily Section 4: These are questions about or have on you. Please fill in each circle to My coughing or breathing is embar | ther effects that you that applies to you assing in public | w mow. | (piratory probi | em may see False O | very hency musual holor, eding a bida, namung, swirmung or playing competitive aports <u>Section 7.</u> We would like to know how your breathing usus filine each circle that applies to you because of <u>your lange</u> . | g fast, O ally affects your daily liferspiratory problem. | |
| My coughing or breathing disturbs. I become exhausted easily Section 4: These are questions about or have on you. Please fill in each circle is My coughing or breathing is embar My langiveprisatory problem is a nu I pain: or get affinal when I cannot | ther effects that y that applies to you sessing in public sence to my family such my breath | v. friends, or no | (piratory probi | om may | very hency measual beloe, refug a bala, nameng, swirmning or playing compective sports Section 7. We would like to know how your breathing true fillish each circle that applies to you because of your long) I cannot play spons or active games I cannot on our few enterimment or recruitment | g fast, or ally affects your daily lij respiratory problem. | re. Pi |
| My coughing or breathing distribe. I become chausted caulity Section 4: These are questions about or have on you. Please fill in each circle is My coughing to breathing is entitled by hugging problem is a nu. I panie or get afraid when I cangot to I feet that I am no in control of my | ther effects that y that applies to you assing in public usance to my family atch my breath hing trapinatory p | v. friends, or no | riratory probl | em may | very hency musual bloor, fiding a bida, naming, swirming or playing competitive sports <u>Section 2.</u> We would like to know hero your breathing using fill-in each circle that applies to you because of <u>your lawn'd</u> I cannot play sports or active games I cannot go out for entertainment or recreation I cannot go out for entertainment or recreation | g fast, O nally affects your daily lift respiratory problem. To O O | (e. P) |
| My coughing or breathing disturbs. I become exhausted easily Section 4: These are questions about or have on you. Please fill in each circle is My coughing or breathing is embar My langiveprisatory problem is a nu I pain: or get affinal when I cannot | ther effects that y that applies to you sessing in public sance to my famil- slach my breath hang respiratory p problem to get an | y, friends, or no roblem | niratory probi | or o | very hency measual beloe, refug a bala, nameng, swirmning or playing compective sports Section 7. We would like to know how your breathing true fillish each circle that applies to you because of your long) I cannot play spons or active games I cannot on our few enterimment or recruitment | g fast, or ally affects your daily lij respiratory problem. | Fe. P1 |
| My coughing or breathing disturbs. I become cubausted easily. <u>Section 6</u> : These are questions about of have an you. Please fill in each circle. My coughing or breathing is emba. My bag bregancies problem is a na. I posic or get afraid when I capacie (first that I am not in control in your I do not expect my lung/respiratory. I have become find or as invalid bec. | my sleep | y, friends, or no roblem | in Contractory problem Con | O O O O O O O O O O O O O O O O O O O | very hency manual bloor, riding a bala, namong, awiraming or playing comperiors report. Section 7. We would like to know how your breathing true fill-in each circle that applies to you because of your longest fill-in each circle that applies to you because of your longest longest 1 cannot play upon to excive games. I cannot go out offer entertunement or recrustion. I cannot go out offer house so do the govery shopping I cannot doe houseleded choor chair: I cannot move far from my bed or chair: Here is all sit of other activities that your least-residentery in | g tus. Otto ally affects your daily life resolutions problem. In Oc | fe. Pl |
| My coughing or breathing distribe. Decoric exhausted easily. Section 6: These are questions about or have an you. Please fill in each circle is. My coughing or breathing is enthus My hangivenizatory problem is an an Junice or get affuid when I cannot I feel that I am not in control of my in a control of the control o | my sleep ther effects that y at applies to you assing in public assect to my family aste my breath aste my propinency p problem to get an same of my langire fron same langirespirate same langirespirate same langirespirate same langirespirate same langirespirate same langirespirate | v, friends, or no roblem ny better sepiratory prob | cighbors (Company) | een may E False 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | very hency manual bloor, refing a bala, namong, awirmana or playing compective sports Section 7. We would like to know how your breathing true fill-in each circle that applies to you because of your lines? I cannot play sports or active games I cannot good offer enterination or recreation I cannot go out of the boute to do the groccey shopping I cannot do bouseledd chows I cannot move far from my bed or chair | g tus. Otto ally affects your daily life resolutions problem. In Oc | (e. P. |
| My coughing or breathing distribed. The coine exhausted easily. Section 6: These are questions about of have on you. Please fill in each circle is My coughing or breathing is embas. My langiveguistic problem in a nutrient point or got affairs when I cannot provide the proof or got affairs when I cannot provide the proof or got affairs when I cannot provide the proof of an expect my lungiveguinary. I have become fail or an invalid be Exercise in out safe for me Everything seems too much of an expect my lungiveguinary. | my sleep ther effects that y at applies to you assing in public assect to my family aste my breath aste my propinency p problem to get an same of my langire fron same langirespirate same langirespirate same langirespirate same langirespirate same langirespirate same langirespirate | v, friends, or no roblem ny better sepiratory prob | riratory probi | on may at False 0 0 0 0 0 0 0 0 0 0 0 0 0 | very hency manual bloor, refing a bala, namong, awirmung or playing compective sports Section 7. We would like to know how your breathing true filter on the first applies to you because of your longs! I cannot play sports or active games I cannot goo out for entertainment or recreation. I cannot go out of the house to do the grocery shopping. I cannot do household choose. I cannot so out of the house to do the grocery shopping. I cannot move his from my hed or claim. Here is all time of other activities that your lung/respiratory y deling. (You do not have no filth on these, they are just to real thorness of breath may affect you! Coing for walls or walking the dog. | g tus. Other affects your daily life resolution problem. In Other Control of the Control of th | (e. P. |
| My coughing or breating distribe. The coine cahasited easily. Section 4: These are questions about or have an you. Please fill in each circle is My coughing or breating in the hard with the hard with the coine of the hard with the coine of the hard with the coine of the coine | my sleep ther effects that y that applies to you assing in public sacce to my family atch my breath theng respirates ppoblem to get an sace of my lungive filort our lungivespirat ing medication, too belp me very | y, friends, or ne ecolism ty better sepiratory peob tory medicating go to Section | Te Contrasory probing the Contrasory probing the Contrasory probing the Contrasory Contr | O O O O O O O O O O O O O O O O O O O | very hency manual bloor, refing a bala, namong, awirmning or playing compective sports Section 7. We would like to know how your breathing true filling on the circle that applies to you because of your longs? I cannot play spons or active games I cannot go out of the choseness or recruition I cannot go out of the house to do the goovery shopping I cannot nove far from my hed or chair Here is a list of other activities that your lung/respiratory p design. (Tou do not have to fill-list indexe, they are just to reminerate of herealth may affect you): Conig for walls or walking the dog Doing activities or chorns at home or in the garden. Having seculal memorane. | g tus. Other affects your daily life resolution problem. In Other Control of the Control of th | fe. Pl |
| My coughing or breating distribe. The coine cubastifed easily. Section 6: These are questions about or have no you. Please fill in each circle in My coughing or breating it of the coine for the hard My has given princip problem is an Ipaic or get afraid when I cannot. I feel that I am not in coatro of my I do not expect my lung/respiratory. I have become fini or an irvalid be Exercise in not safe for me. Everything seems soo much off an Everything seems soo much off an April 1. These are questions about y inhaloses, and palls. If you are not received that applies no you min. My hang represented y medication doe I get embarrassood using my langles have unglessant due effects from have considered from the constraint of the constraints. | my sleep her effects that y hat applies to you assing in public sance to my family satch my breath hang respiratory p problem to grow problem awase of my hangire fifort the langirespiration are langirespiration ing medication, took belp me very piratory medication to belp me very piratory medication. | w. mow. y. friends, or no roblem ty better supiratory prob tory medicatin go to Section much much in public y medication | Te Constitute problem Constitute | om may set False 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | very hency mensual bloor, refing a balas, nameng, awirmans or playing compective sports Section 7. We would like to know how your breathing game fill-in each circle that applies to you because of your lound like to you because of your lound like to go to the process of your lound like to go to the process of lounds on the contribution of lounds go out for encuraturement or recreation. I cannot go out for encuraturement or recreation a cannot do bousehold chores. I cannot now hat from my bed or chair lounds on the process of the process of the contribution o | g tus. Other affects your daily life resolution problem. In Other Control of the Control of th | fe. Pl |
| My coughing or breating distribe. The coine cahasited easily. Section 4: These are questions about or have an you. Please fill in each circle is My coughing or breating in the hard with the hard with the coine of the hard with the coine of the hard with the coine of the coine | my sleep her effects that y hat applies to you assing in public sance to my family satch my breath hang respiratory p problem to grow problem awase of my hangire fifort the langirespiration are langirespiration ing medication, took belp me very piratory medication to belp me very piratory medication. | w. mow. y. friends, or no roblem ty better supiratory prob tory medicatin go to Section much much in public y medication | intratury probi | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | very hency manual bloce, refing a bala, namong, swirmann or playing comperiors report. Section 7. We would like to know how your breathing true fill-in each circle that applies to you because of your hund! I cannot play sports or active games I cannot goo out of entertuinment or recreation. I cannot go out of the house to do the goocy shopping I cannot do be bouseled closers. I cannot now hat from my hed or dain: Here is all sit of other activities that your lung/respiratory p deding. (You do not have to fill-in these, they are just to rem shortess of breath may affect you'll.) Coing for walks or walking the dog. Ding advision or chorns at home or in the gurden. Coing to charth, or a place of entertuinment. | g tus. Other affects your daily life resolution problem. In Other Control of the Control of th | fe. Pl |
| My coughing or breathing distribe. The coine cubastifed easily. Section 6: These are questions about of have on you. Please fill in each circle is My coughing or breathing is embas. My long tropping or breathing is embas. My long tropping or proceedings is embas. The control of the control of the country | my sleep her effects that y att applies to you att applies be to the the the the the the the the | w now. y, friends, or ne roblem toblem ty better ty better tory medication or in public to much to medication a loc imight be affi | priratery problem Continuous problem Continuous Conti | om may E Files O O O O O O O O O O O O O O O | very hency manual bloor, riding a balan, namong, swirmning or playing competitive sports Section 7. We would like to be have how your breathing true filters each circle that applied to you because of your longed. I cannot play sports or active games I cannot go out of the meaturement or recreation. I cannot go out of the house to do the grocery shopping I cannot do bousehold chown for white it cannot move that from my hed or chair Here is it till of other activities they pure languisation you deduce. (You do not have to fill his these, they are just to rem theorems of portant many affect you): Ooing for wallso or walling the dog. Doing activities or choese at home or in the guiden Having cannot measure. Going to charth, or a place of entrainment Conty to charth, or a place of our money chosen County to charth, or a place of our money chosen County to charth, or a place of our money chosen County to them to many orther important activities that the Please with in any other important activities that the please with in my other important activities that you harplying the higher of Please with in any other important activities that you harplying the higher of Please with in any other important activities that you harplying the higher of the place of the propring with higher of the place of the propring with higher of the place of t | ally affects your daily ill ally affects your daily ill residenticy archive. You Go Go Go Go Go Go Go Go Go | E E E C C C C C C C C C C C C C C C C C |
| My coughing or breating distribe. The coine calculated easily. Section 4: These are questions about or have an you. Please fill in each circle in the mean of the coine for the mean of the please fill in each circle in My coughing or breating in clienter My hangivenience problem is an I pain or get a fraid when II cancer. I feel that I am not in control of my I do not expect my lung/respiratory. I have become final or an invalid be Exercise is not safe for me Everything seems so much of an exception of the mean of th | my sleep. her effects that p she stat applies to you assing in public, as you asson to my family anche my breath and the my breath, and the my breath and t | w now. y, friends, or ne roblem toblem ty better ty better tory medication or in public to much to medication a loc imight be affi | priratery problem Continuous problem Continuous Conti | om may E Files O O O O O O O O O O O O O O O | very hency manual bloor, noting a bake, namong, swirmning or playing competitive sports Section 7. We would like to know how your breathing tun fill-in each circle that applies to you because of your long? Leanest play spons or active games Leanest goo out five enterinationer or recruition Leanest go out of the house to do the grocery shopping Leanest do boueshold chooses Leanest move that from my bed or chair Here is a list of other activities that your lung/respiratory p destry, (You do not have to fill-list inkees, they are just to rem shormess of breath may affect you): Coing for walks or walking the dog Doing activities or chores a brone or in the guiden Hering manual to a place of entertainment Going on in bad weather or not survely recent Visiong family or friends or playing with children | ally affects your daily ill ally affects your daily ill residenticy archive. You Go Go Go Go Go Go Go Go Go | E E E C C C C C C C C C C C C C C C C C |
| My coughing or breating distribe. The coine cahasited easily. Section 4: These are questions about or have an you. Please fill in each circle in My coughing or breating it can be made My hang respiratory problem is an Ipsuice or get afraid when I cannot. I feel that I am not in control of my I do not report my lung/respiratory. I have become fini to cast of one Exercise is not safe for me Everything seems soo much of an except in the Company of the Co | my sleep. her effects that y hat applies to you saving in public savour to my family saving in public savour to my family speciatory by problem to get as use of my hamily see from sur lung/respirator sur lung/respirator sur lung/respirator sur lung/respirator problems y lung/respirator y lung-respirator y lung-respi | w now. y, friends, or ne roblem toblem ty better ty better tory medication or in public to much to medication a loc imight be affi | niratory probi | on may E Files O O O O O O O O O O O O O O O O O O O | very hency manual bloor, riding a balan, namong, swirmning or playing competitive sports Section 7. We would like to be have how your breathing true filters each circle that applied to you because of your longed. I cannot play sports or active games I cannot go out of the meaturement or recreation. I cannot go out of the house to do the grocery shopping I cannot do bousehold chown for white it cannot move that from my hed or chair Here is it till of other activities they pure languisation you deduce. (You do not have to fill his these, they are just to rem theorems of portant many affect you): Ooing for wallso or walling the dog. Doing activities or choese at home or in the guiden Having cannot measure. Going to charth, or a place of entrainment Conty to charth, or a place of our money chosen County to charth, or a place of our money chosen County to charth, or a place of our money chosen County to them to many orther important activities that the Please with in any other important activities that the please with in my other important activities that you harplying the higher of Please with in any other important activities that you harplying the higher of Please with in any other important activities that you harplying the higher of the place of the propring with higher of the place of the propring with higher of the place of t | ally affects your daily ill ally affects your daily ill residenticy archive. You Go Go Go Go Go Go Go Go Go | E E E C C C C C C C C C C C C C C C C C |
| My coughing or breating distribe. The coine character cashy. Section 6: These are questions about or have an you. Please fill in each circle in My coughing or breating it can be comed. My hang respiratory problem is an Ipanic or get afraid when I cannot. I feel that I am not in control of my I do not expect my lung/respiratory. I have become fini or an irvalid be Exercise in not safe for me. Exercise is not safe for m | my sleep. her effects that y her effects that y hat applies to you saving in public saving | w men; y, friends, or ne coolern y better y better spiratory medicati go to Section much much might be affi- parts applies to do it. | ofrastory probi | on may ten may ten may ten file 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | very hency manual bloor, noding a bake, namong, awiranian or playsing compective sports Section 7. We would like to know how your breathing true filling neath circle that applies to you because of your long? I cannot play spons or active games I cannot go out of the house to do the gooccy shopping I cannot do houselood chown or continued to the control of the c | g flut. Other street sour daily it is a second and the second and | fe. Pl |
| My coughing or breating distribe. The coine character casity. Section 6: These are questions about or have no you. Please fill in each circle to My coughing or breating it is each circle to My toughing or breating problem is an Ipanic or get afraid when I cannot. I feet that I am not in coarso of my I do not expect my lung/respiratory. Have become fini to cast of one. Everything seems soo much of an except in the company of the company | my sleep. ther effects that y that applies to you not you have you you have you have you have you will not you you will not you you with you you will not you you you will not you you will not you you will not you | s new. y, friends, or no eroblem yy better yy better tory medicatio go to Section or much so in public y medication a to public is might be aff parts applies to do it. to do it. to do it. to do it. | In Contrastry problem Contrastry problem Contrastry problem Contrastry problem Contrastry Contrastr | on many em many em many em place o o o o o o o o o o o o o o o o o o o | very hency manual bloor, riding a balan, namong, swirmning or playing competitive sports Section 7. We would like to know how your breathing true fill-in each circle that applies to you because of your longest fill-in each circle that applies to you because of your longest longest I cannot goo ut for entertainment or reversition. I cannot go out of the house to do the govery shopping I cannot do beoughed close of white I cannot move far from my bed or chair. Here is all sit of other activities they your long-respiratory p deday. (You do not have to fill-in these, they are just to rem shorteness of breath may affect you.) Coing for walks or walking the dog. Doing activities or chores at home or in the guiden library great intercome. Going on in bad weather or into unely recent Vising family or friends or playing with children. Please write in any other important activities that your langives doing. | g flut. Other affects your daily it gets to excellent the second to the | fe. Pi |
| My coughing or breathing distribe. The corte cubastified easily. Section 4: These are questions about or have on you. Please fill in each circle is My coughing or breathing it enthat My hangivenization problems in an I pain or get a fluid when I cancer I feel that I am not in control of my in I on or expect my lung/respiratory. I have become final or an invalid because the control of the Exercise is not safe for me Excepting the many control of the Exercise is not safe for me Excepting of the many control of the Exercise is not safe for me Excepting of the Exercise are questions about y inhalors, and pills. If you are not received that any pills. If you are not received that any pills are you men. My hangivenizatory medication doe I get embarrasseod using my happiers have unglessee to you men. Section 6. These are questions about he problem. For each question, answer I have unglesseen. Otherwise answer I lake he long time to get variety and the Problem. The reach question is answer I lake he long time to get variety and the I had to debove, or I built shower than other good of trans. I he I will shower than other good of trans. | my sleep. her effects that y her effects that y at applies to you some jo not be some to my family some you have jorden to you have jorden to you have jorden to get an asset of my have have jorden to get an asset of my have have you have have you have have you have have have have have have have have | s new. y, friends, or no eroblem yy better yy better tory medicatio go to Section or much so in public y medication a to public is might be aff parts applies to do it. to do it. to do it. to do it. | In Contrastry problem Contrastry problem Contrastry problem Contrastry problem Contrastry problem Contrastry C | on many see False 10 0 | very hency manual bloor, nding a bake, namong, swirmning or playing competitive sports Section 7. We would like to know how your breathing true filters each circle that applies to you because of your longed. I cannot play sports or active games I cannot go out of the meaturement or recreation. I cannot go out of the house to do the grocery shopping I cannot do household chown for the cannot go out of the house to do they grocery shopping I cannot move the from my hed or chair Here is all till of other activities that pure langivespicatory p deday. (You do not have to fill in these, they are just to rem thorness of breath may affect you): Coing for walls or walling the dog. Doing activities or choese at home or in the guiden Histing social intercourse. Going on them, or a place of entertainment Coing on them, or a place of entertainment Coing on the she when or is no smody recent Vanling limity or franch or playing with children Finas write in any other important activities that your hanging doing. New, would you fill in the electe (only one) that you think it problem affects you. It does not stop me from doing anything I would like to of the does not stop me from doing anything I would like to of the does not stop me from doing anything I would like to of the does not stop me from doing anything I would like to of the does not stop me from doing anything I would like to on the problem affects you. | g flat. O lastly affects your daily it is remainstery, architects. To complete the complete th | fe. Pl Co Co Co Co Co Co from h you breat |
| My coughing or breating distribe. The corte cubastifed easily. Section 4: These are questions about or have on you. Please fill in each circle in the control of the contr | my sleep. her effects that y her effects that y har applies to you souling in public souling in public souling in you have instead my breath. has inspiratory problem to get an use of my hampire problem to get an use of my hampire the inspiratory medicated ing medication, on thelp me very puratory medicate your activities we your activities we your activities the ferme with my lafe decided takes a long time t sage, or I stop to or age, or I stop | s new. y, friends, or ne roblem y better tory medicati go to Section much much mich be affi parts applies to do it. to do it. | In Contrastry problem Contrastry problem Contrastry problem Contrastry problem Contrastry problem Contrastry C | on may in Phile in O | very hency manual bloor, nding a bala, namong, swirmning or playing competitive sports Section 7. We would like to know how your breathing tax fillen each circle that applies to you because of your lenge? I cannot play sports or active games I cannot goo us of the entertainment or recreation. I cannot go out of the house to do the grocery shopping I cannot do household chosen. I cannot show hold to the house to do the grocery shopping I cannot move the from my hed or chair. Here is a tist of other activities that your lange respiratory y deding. (You do not have no fill to these, they are just to remthorness of breath may affect your. Coing for walks or walking the dog. Doing activities or chores at home or in the gurden Having sexual mentioners. Going to thereth, or a place of entertainment Going to thereth, or a place of one textuinment Going to thereth, or a place of one textuinment Going to the house which is a place of the contraction. Pileas write in any other important activities that your hangless doing. New, would you fill in the electer (only one) that you think it problem affects your. In the sex of stop me from doing anything I would like to the house you do the things I would like to the lings I | g flat. ally affects your daily if it is resistance, archive. To complete the com | you fi |
| My coughing or breating disturbs. The coine cahasited easily. Section 4: These are questions about or have an you. Please fill in each circle in My coughing or breating it is care in circle in My hangivenizatory problem is an Ipsuice or get a triast when I cannot I feet that I am not in control of my I do not report my lump/steprintory. I have become fini to cate of one Exercise is not safe for me Exercise in the Section of Exercise is not safe for me Exercise in the Section of Exercise is not safe for me Exercise in the Section of Exercise is not safe for me Exercise in the Section of Exercise is not safe for me in the Exercise in the Exercise is not safe for me in the Exercise in the Exercise is not safe for me in the Exercise in Exe | my sleep. there effects that y put at applies to you souling in public so you souling in public so souling in public souling in public sance to my family sould my breath. The public share you want to my breath hang's respiratory problem to get an usus of my hang's reproblem to get an usus of my hang's reproblem to get an usus of my hang's reprinted the public state of my hang's reprinted the public state of my hang's reprinted the public state of the public sta | s new. y, friends, or ne roblem y better to y better to y better to y service prob to y medication nuch much much might be affile parts applies to do it. vii. to do it. stop to stop to stop to stop to stop to stop to stop to stop to stop to stop to stop to stop to stop to stop s | including problem (Continue) problem (Continue) problem (Continue) | on many Er Fields O O O O O O O O O O O O O O O | wey hency manual bloor, nding a bala, namong, awiraming or playing competitive sports Section 7. We would like to know how your breathing true fill-in each circle that applies to you because of your long? I cannot go out of the contention or recruition I cannot go out of the house to do the grocery shopping I cannot do houselold clowers I cannot move far from my bed or chair Here to a list of other activities that your lung/respiratory p doing, (Tou do not have to fill-lin these, they are just to rem shormess of breath may affect you?) Coing to walk or walking the dog Doing activities or charms a home or in the garden Having excell introcure Going to charth, or a place of entertainment Going to tharth, or a place of entertainment Going to in bad weather on the surely, room Vuleng family or friends or playing with children Please write in any other important activities that your langing New, would push fill in the clothe (only one) that your shail be problem affects you: It does not stop me from doing anything I would like to the top to found one or two things I would like to the top the found one or two things I would like to the top the found one or two things I would like to the top the found of the control of the problem of the other form doing one or two things I would like to the top the found of the control of the problem of the control of the problem of the control of the problem of the other of the control of the problem of the other of the other of the problem of the other of the other of the problem of the other | ally affects your daily ii) sessionistics architem. To Co Co Croblem may prevent you printerly problem may stop printerly problem may stop best describes how your To Co Co Co Co Co Co Co Co Co | fe, Pl from E from from from from from from from from |
| My coughing or breating distribe. The coine calculated easily. Section 4: These are questions about or have an you. Please fill in each circle in My coughing or breating it can be comediated. My happrespicatory problem is an Ipsaic or get afraid when I cannot. I feel that I am not in control of my I do not report my lump/respiratory. I have become fini or an irvalid be Exercise is not safe for me Everything seems soo much of an in except only inhabers, and pills. If you are not receive that applies to so safe for me in the control of the problem. The area of questions about y inhabers, and pills. If you are not received that applies to you men. My hangivenimory medication doe I get embarrassood using my happer have unpleasant doe effects from My hangivenimory medication into I get embarrassood using my happer photon. For each question, a sever To breathing problem. Gibernside answer I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take to long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or I take a long time to get washed or the get washed to get the long time to get washed or the get washed to get the get take the get | my sleep. ther effects that y har applies to you souling in policy cannot be my furnily and my | y, friends, or ac ecoloris y, friends, or ac ecoloris yo better superintery pecc tory medicatin go to Section in public in i | including problem (Continue) problem (Continue) problem (Continue) | on many see False 10 0 | very henry manual bloor, nding a bala, namong, awiranian or playing competitive sports Section 7. We would like to know how your breathing true filling neath circle that applies to you because of your long? I cannot play spont or active games I cannot go out of the house to do the gooccy shopping I cannot do houselved chowners or recruition. I cannot nove fine from my hed or chair Here is a list of other activities that your lung/respiratory p slong, (Tou do not have to fillful nature, they are just to reminstrances of breath may affect you). Coing for walls or walking the dog. Doing activities or shoen at home or in the gurden. Having social intensives. Coing to charth, or a place of entertuinment Coing on in bad weather or into uracky rooms. Vasing family or floated or playing with children. Please write in any other important activities that your langives doing. Now, would you fill in the clotde (only one) that you think it problem affects you: It does not stop me from doing anything I would like to of it stops me from doing once or two things! would like to of it stops me from doing everyding! would like to the suppare from doing everyding! would like to the suppare from doing everyding! would like to the suppare from doing everyding! | ally affects your daily it is a second and the seco | you fi |
| My coughing or breating distribe. The coine character casisty. Section 6: These are questions about or have an you. Please fill in each circle in My coughing or breating it can be comed by hard preprintey problem is an Ipaic or get afraid when I cannot. I feel that I am not in control of my I do not expect my lung/respiratory. I have become fini or an irvalid be Exercise is not safe for me Excepting location in control of my I do not expect my lung/respiratory. Have become fini or an irvalid be Exercise is not safe for me Exercise in the area of questions about his plant and the safe of the Exercise is not safe for me Exercise in the safe are questions about his problem. For each questions answer Travelling problem. For each questions, answer Travelling problem. For each questions, answer Travelling problem. Getherotte answer I take a long time to get washed or learnot take a bath or shower, or I walk shower than other people my folss such as household chores take III walk up one flight of states. I have to not My breathing problem makes it diff withing up to the safe of the problem makes it difficancying benefits question in the problem makes it difficancying benefit on the problem makes it difficancying benefits question to the problem makes it difficancying benefit question to the problem makes it difficancying benefits question to the problem makes it difficancying benefit question to the problem makes it difficancying benefit question to the problem makes it difficancy in the problem | my sleep. ther effects that y hat applies to you seem to plant applies to you seem to provide the your and the your and the your and the young to the your and the young to t | w ment, y, friends, or ne ecoloris y, friends, or ne ecoloris yo better supprintery peoc tory medicatin go to Section trach on in public in in public in might be aff perts applies to do it cost assection save to stop to stop to stop to stop super to stop | In the state of th | on may in File on may in File on on one on one on one on one on one one | very hency manual bloor, refing a bala, namong, swirmning or playing competitive sports Section 7. We would like to know how your breathing true fill-ine each circle that applies to you because of your breath and I cannot play upon to active games. I cannot play upon to active games. I cannot go out of the meaturement or recrusion. I cannot nove that from my bed or other cannot go out of the boate to do the govery shopping I cannot do boate-bold chown from the first pour long/respicatory p deday. (Fou do not have to fill-in these, they are just to rem shorteness of breath and affect play a long prespicatory p deday. (Fou do not have to fill-in these, they are just to rem shorteness of breath and affect of chorse at bottom or in the garden Having scalar intercoarse. Coing for walks or walking the dog. Doing activities or chores at bottom or in the garden Having scalar intercoarse. Coing to which, or a play or into unolys rooms. Visiong family or friends or playing with children Please write in any other important activities that your hangives doing. Now, would you fill in the circle (only one) that you think it problem affects you: It does not stop me from doing anything I would like to d It stops me from doing one or two things! would like to the stops use from doing one of the things! weld the to It stops me from doing one of the things! weld the to It stops me from doing one of the things! weld the to | g flat. Outly affects your daily if the secondary resolution resolution. Outly affects your daily if the secondary resolution resolution. Outly affects are prevent you will be resolved as well as which you of ways in | you fi |
| My coughing or breathing distribe. The corte cubastified easily. Section 6: These are questions about or have an you. Please fill in each circle is My coughing or breathing is enthat My hangivenization problem in a survey of the country of the c | my sleep. ther effects that y hat applies to you seem to plant applies to you seem to provide the your and the your and the your and the young to the your and the young to t | w ment, y, friends, or ne ecoloris y, friends, or ne ecoloris yo better supprintery peoc tory medicatin go to Section trach on in public in in public in might be aff perts applies to do it cost assection save to stop to stop to stop to stop super to stop | including problem (Continue) problem (Continue) problem (Continue) | on may in File on may in File on on one on one on one on one on one one | very henry manual bloor, nding a bala, namong, awiranian or playing competitive sports Section 7. We would like to know how your breathing true filling neath circle that applies to you because of your long? I cannot play spont or active games I cannot go out of the house to do the gooccy shopping I cannot do houselved chowners or recruition. I cannot nove fine from my hed or chair Here is a list of other activities that your lung/respiratory p slong, (Tou do not have to fillful nature, they are just to reminstrances of breath may affect you). Coing for walls or walking the dog. Doing activities or shoen at home or in the gurden. Having social intensives. Coing to charth, or a place of entertuinment Coing on in bad weather or into uracky rooms. Vasing family or floated or playing with children. Please write in any other important activities that your langives doing. Now, would you fill in the clotde (only one) that you think it problem affects you: It does not stop me from doing anything I would like to of it stops me from doing once or two things! would like to of it stops me from doing everyding! would like to the suppare from doing everyding! would like to the suppare from doing everyding! would like to the suppare from doing everyding! | g flat. Outly affects your daily if the secondary resolution resolution. Outly affects your daily if the secondary resolution resolution. Outly affects are prevent you will be resolved as well as which you of ways in | you fi |
| My coughing or breating distribe. The coine character casisty. Section 6: These are questions about or have an you. Please fill in each circle in My coughing or breating it can be comed by hard preprintey problem is an Ipaic or get afraid when I cannot. I feel that I am not in control of my I do not expect my lung/respiratory. I have become fini or an irvalid be Exercise is not safe for me Excepting location in control of my I do not expect my lung/respiratory. Have become fini or an irvalid be Exercise is not safe for me Exercise in the area of questions about his plant and the safe of the Exercise is not safe for me Exercise in the safe are questions about his problem. For each questions answer Travelling problem. For each questions, answer Travelling problem. For each questions, answer Travelling problem. Getherotte answer I take a long time to get washed or learnot take a bath or shower, or I walk shower than other people my folss such as household chores take III walk up one flight of states. I have to not My breathing problem makes it diff withing up to the safe of the problem makes it difficancying benefits question in the problem makes it difficancying benefit on the problem makes it difficancying benefits question to the problem makes it difficancying benefit question to the problem makes it difficancying benefits question to the problem makes it difficancying benefit question to the problem makes it difficancying benefit question to the problem makes it difficancy in the problem | my sleep. ther effects that y hat applies to you seem to plant applies to you seem to provide the your and the your and the your and the young to the your and the young to t | w ment, y, friends, or ne ecoloris y, friends, or ne ecoloris yo better supprintery peoc tory medicatin go to Section trach on in public in in public in might be aff perts applies to do it cost assection save to stop to stop to stop to stop super to stop | In the state of th | on may in File on may in File on on one on one on one on one on one one | very hency manual bloor, refing a bala, namong, swirmning or playing competitive sports Section 7. We would like to know how your breathing true fill-ine each circle that applies to you because of your breath and I cannot play upon to active games. I cannot play upon to active games. I cannot go out of the meaturement or recrusion. I cannot nove that from my bed or other cannot go out of the boate to do the govery shopping I cannot do boate-bold chown from the first pour long/respicatory p deday. (Fou do not have to fill-in these, they are just to rem shorteness of breath and affect play a long prespicatory p deday. (Fou do not have to fill-in these, they are just to rem shorteness of breath and affect of chorse at bottom or in the garden Having scalar intercoarse. Coing for walks or walking the dog. Doing activities or chores at bottom or in the garden Having scalar intercoarse. Coing to which, or a play or into unolys rooms. Visiong family or friends or playing with children Please write in any other important activities that your hangives doing. Now, would you fill in the circle (only one) that you think it problem affects you: It does not stop me from doing anything I would like to d It stops me from doing one or two things! would like to the stops use from doing one of the things! weld the to It stops me from doing one of the things! weld the to It stops me from doing one of the things! weld the to | g flat. Outly affects your daily if the secondary resolution resolution. Outly affects your daily if the secondary resolution resolution. Outly affects are prevent you will be resolved as well as which you of ways in | you fi |

Diary Card for Asthma Symptoms

| Parameter | Finding | Score |
|---|---|-------|
| sleep disturbance | no sleep disturbance due to asthma | 0 |
| | awoken once during the night for less than an hour because of asthma | 1 |
| | awoken two or three times or once for more than an hour because of asthma | 2 |
| | awake most of the night because of asthma | 3 |
| chest tightness on awakening | not present and didn't require extra bronchodilator during the night | 0 |
| | not present but did require extra bronchodilator during the night | 1 |
| | present | 2 |
| duration and frequency of daytime wheeze and breathlessness | none | 0 |
| | occasional | 1 |
| | frequent but not all day | 2 |
| | most or all of the day | 3 |
| severity of daytime wheeze and breathlessness | none | 0 |
| | mild; not incapacitating or distressing | 1 |
| | moderate to severe; distressing and/or had to limit activities | 2 |
| cough | none | 0 |
| | occasional | 1 |
| | more than occasional | 2 |