

## Evidence Table 9. Control of Factors Affecting Asthma: Allergen Avoidance

### Abbreviations used in table:

<b>Bla g1</b>	<b>Cockroach allergen</b>
<b>Can f1</b>	<b>Dog allergen</b>
<b>Der f1</b>	<b>D. farinae</b>
<b>Der p1</b>	<b>Dermatophagoides pteronyssinus</b>
<b>Der p2</b>	<b>Dermatophagoides pteronyssinus</b>
<b>eNO</b>	<b>exhaled nitric oxide</b>
<b>FEF<sub>25-75</sub></b>	<b>forced expiratory flow between 25% and 75% of the vital capacity</b>
<b>FEV<sub>1</sub></b>	<b>forced expiratory volume in 1 sec</b>
<b>FVC</b>	<b>forced vital capacity</b>
<b>HEPA</b>	<b>high efficiency particulate air</b>
<b>PEF</b>	<b>peak expiratory flow</b>
<b>RV</b>	<b>residual volume</b>
<b>VC</b>	<b>vital capacity</b>

\* indicates primary outcome

### Evidence Table 9. Control of Factors Affecting Asthma: Allergen Avoidance

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
Ehnert et al. Reducing domestic exposure to dust mite allergen reduces bronchial hyperreactivity in sensitive children with asthma. J Allergy Clin Immunol 1992;90(1): 135-138.	Randomized controlled trial	To examine whether a biologically significant mite-allergen reduction can be achieved in the domestic environment	24 (23)	<b>Age</b> 7-15 yr; median 10 yr <b>Gender</b> Not reported <b>Ethnicity</b> Not reported	Mild or moderate bronchial asthma according to American Thoracic Society definition Hypersensitivity to Der p1 and Der f1	<b>Arm 1 (E)</b> Polyurethane-coated encasing of mattresses, comforts, and pillows in combination with treatment of carpets with tannic acid (n=8; n=8 completers) <b>Arm 2 (BB)</b> Treatment of mattresses and carpets with the acaricide benzyl benzoate (n=8; n=8 completers) <b>Arm 3 (P)</b> Mattresses treated with placebo foam and powder (n=8; n=7 completers)	Treated at baseline and at 4 and 8 months; data collected at days 0 and 14 and at months 4, 8, and 12.	BB and P did not result in significant reduction of mite allergen; significant decrease in mite allergen on mattresses in E (p<0.005) with 91% decreased by day 14 (p<0.05) rising to 98% by month 12.	Nonsignificant decrease in PC <sub>20</sub> for P, no change in BB, and increase only in E (between groups comparison, p<0.05). Within E, PC <sub>20</sub> increased at months 8 and 12 (p<0.05) with 2.2-fold increase in month 4, 4.5-fold increase in month 8, and 2.7-fold increased in month 12.		

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
<p>Van der Heide et al. Allergen reduction measures in houses of allergic asthmatic patients: effects of air cleaners and allergen-impermeable mattress covers. <i>Eur Respir J</i> 1997;10(6): 1217–1223.</p> <p>(Philips Domestic Appliances &amp; Personal Care, Groningen, The Netherlands)</p>	<p>Randomized, double-blind, parallel groups design</p>	<p>To test recently developed air cleaners with respect to their capacity to capture airborne allergen particles and to improve clinical parameters of patients with asthma sensitized to aeroallergens</p>	<p>45 (45)</p>	<p><b>Age</b> 18–45 yr, mean = 32 yr</p> <p><b>Gender</b> 37.8% male, 62.2% female</p> <p><b>Ethnicity</b> Not reported</p> <p><b>Smoking</b> None were smokers</p> <p><b>Environmental Exposure</b> Presence of animals, 33.3% Smoking by coresidents, 33.3% Textile floor covering in living room, 80% Textile floor covering in bedroom, 57.8%</p>	<p>Mild asthma History of airway hyperresponsiveness</p> <p>Positive intradermal skin test: 24.4% to house-dust mite alone, 68.9% to house-dust mite and pollen, 57.8% to house dust and pets, 48.9% to all three</p> <p>FEV<sub>1</sub> % pred., range 69–124, mean = 94</p> <p>PC<sub>20</sub> histamine mgmL<sup>-1</sup>, range 0.08–124, mean = 7.27</p>	<p><b>Arm 1</b> Active air cleaners in living rooms and bedrooms with air filtered by a coarse prefilter followed by a rota-filter, and then high efficiency particulate air (HEPA)-type filter (G1) (n=15)</p> <p><b>Arm 2</b> Placebo air cleaners plus allergen-impermeable mattress and pillow covers (G2) (n=15)</p> <p><b>Arm 3</b> Active air cleaners plus mattress and pillow covers (G3) (n=15)</p>	<p>12 months; dust samples collected at 3 and 6 months, and dust from air cleaner filters collected at 12 months.</p>	<p>Amount of mattress dust decreased in G2 (p&lt;0.05) and G3 (p&lt;0.01) (with mattress covered) with no decrease in G1 (p&gt;0.05) (no mattress cover).</p> <p>Amount of airborne dust captured in filters showed large variation: mean = 6.77 g dust in living room and 2.39 g dust in bedroom; mean = 511 ng Der p1 in living room and 485 in bedroom. Concentration in floor dust (geometric mean) was 797 at baseline and 420 ng/g at 6 months (p&lt;0.01) and 1,122 and 739 ng/g for bedrooms (baseline and 6 months, p&lt;0.01). No difference between groups.</p> <p>Passive smoking vs. no smoking differed in amount of dust in HEPA-type filter in living room (8.17 vs. 3.40, p&lt;0.001) but not in bedroom (2.38 vs. 2.01, p&gt;0.05).</p>	<p>Morning and evening PEF did not change during the study. Improvement in peak flow variation from baseline to 6 months was correlated with amount of dust and house-dust-mite allergen collected in the filters (r=0.43, p=0.005).</p>	<p>Improvement in PC<sub>20</sub> histamine found only in G3 (p&lt;0.05) but only 1 doubling dose. 32% of variance of change in PC<sub>20</sub> histamine between baseline and 6 months was explained by treatment group (p=0.005), change in Der p1 in mattress dust (p=0.002), floor covering in the living room (p=0.014), and presence of cats/dogs (p=0.020).</p>	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
Carter et al. Home intervention in the treatment of asthma among inner-city children. J Allergy Clin Immunol 2001;108(5): 732-737. (National Institutes of Health)	Randomized, single-blind, placebo control group design	To investigate whether implementing low-cost measures for indoor allergen avoidance could reduce the number of sick days and unscheduled visits to health care facilities for asthma	104 (104)	<b>Age</b> 6-16 yr, mean = 10.9 yr <b>Gender</b> Not reported <b>Ethnicity</b> Not reported (clinic population is 92% African American)	All being treated for asthma 49.4% receiving inhaled controller medications Sensitization of children: dust mite 74%, cockroach 56%, cat 26%, <i>Alternaria</i> species 28%, <i>Aspergillus fumigatus</i> 18%, seasonal only 2%, seasonal with indoor 45%	<b>Arm 1</b> Avoidance (A) Allergen-impermeable mattress and pillow covers, effective roach bait, instructions to wash bedding once a week in hot water, instructions about cleaning to control dust mites and cockroaches (n=35; n=30 completers) <b>Arm 2</b> Placebo (P) Allergen-permeable mattress and pillow covers, ineffective roach traps, instructions to continue normal practice of washing bedding in cool/cold water (n=34; n=25 completers) <b>Arm 3</b> Control (C) Allergen-control measures not discussed (n=35; n=30 completers)	12 months; home visits at 3, 8, and 12, months for A and P and at 12 months for C. 1 yr before enrollment to 3-month visit considered before and 3 months to 18 months considered after period for assessment of acute visits using self-report and hospital and clinic charts.	Decrease of mite allergen (>70% over 4 visits) seen in 1/3 of homes with no difference between A and P.		Decrease in acute visits for A (51% to 34%) and P (64% to 45%) vs. C (45% to 48%) (p<0.001). Children allergic to and exposed to mite who had a significant decrease in mite allergen showed decrease in acute visits (11/17 vs. 3/12, p=0.035). Decrease in cockroach allergen not associated with change in acute visits.	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
Htut et al. Eradication of house dust mite from homes of atopic asthmatic subjects: a double-blind trial. <i>J Allergy Clin Immunol</i> 2001;107(1): 55–60. (Mediclean Corporation Ltd, Leeds, United Kingdom; NUAIR, Ltd, Caerphilly, United Kingdom)	Randomized, double-blind, placebo-controlled trial	To determine whether combined steam and heat treatment of home furnishings reduced bronchial hyperreactivity of patients with asthma and lowered house-dust-mite antigen loads	30 (30 for allergen data; 23 for clinical data)	<b>Age</b> 18–45 yr <b>Gender</b> Not reported <b>Ethnicity</b> Not reported	Wheal of $\geq 3$ mm in diameter to house-dust-mite antigen $\geq 15\%$ rise in FEV <sub>1</sub> after 200 mcg inhaled salbutamol No patients with cat at home who were allergic to cats	<b>Arm 1</b> Cleaning (G1) Carpets and upholstery steam cleaned; mattresses cleaned with hot air (110°C); new pillows provided; linen washed using 60°C (n=10; n=7 completers) <b>Arm 2</b> Cleaning + Ventilation (G2) Cleaning as above + positive ventilation system installed in loft above bedroom (n=10; n=8 completers) <b>Arm 3</b> Sham (G3) Cleaning with same equipment but without heat and steam (n=10; n=8 completers)	12 months after 4-week run-in period	Log-transformed Der p1 for mattress changed between groups across time (p=0.03). Level in G1 fell by 6-fold from 10.4 mcg/g, remained low for 6 months, went back to 1.5-fold at 12 months. In G2, levels were reduced by 11-fold from baseline of 14 mcg/g and remained below 1.6 mcg/g throughout study period. In G3, no changes from baseline level of 6.7 mcg/g.  In G1 and G2, Der p2 concentrations fell progressively after mite eradication, but not with G3 (p=0.001).		Log-transformed histamine PD <sub>20</sub> changed with time (p=0.05): rose 4-fold by 9 months in G1, 4-fold improvement seen by 3 months in G2 and sustained for 12 months; $\leq 2$ -fold change at 6 months in G3. No results for time by group changes reported.	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
Peroni et al. Mite avoidance can reduce air trapping and airway inflammation in allergic asthmatic children. Clin Exp Allergy 2002;32(6): 850–855.	Single group descriptive study (Residents in the Istituto Pio XII, Misurina, Italy)	To investigate whether anti-inflammatory therapy and effective allergen avoidance could ameliorate the pattern of air trapping and whether this phenomenon could be accompanied by a parallel reduction of eNO as index of airway inflammation	18 (18)	<b>Age</b> 7–13 yr, mean = 10.7 yr <b>Gender</b> 94% male; 6% female <b>Ethnicity</b> Not reported	Moderate-to-severe asthma All receiving regular anti-inflammatory drugs: 66.7% fluticasone and 33.3% budesonide Positive skin-prick test to house-dust mite Positive RAST score >3	Children stayed at high altitude in Misurina for the scholastic year (September to June) and went home for 15 days in December/January. Regular therapies were gradually withdrawn within a few weeks due to symptomatic improvement. During time at home, they received preventive regular treatment with inhaled steroid (fluticasone 300 mcg/day) that was gradually withdrawn after return to the institute.			RV decreased after 3 months of stay (117.5 to 96.5, p<0.02), increased after allergen-reexposure (96.5 to 126.2, p<0.03), and decreased after 6 months (126.2 to 91.1, p=0.001). FEV <sub>1</sub> , FEF <sub>25–75</sub> , and VC did not differ between periods. eNO decreased after 3 months at high altitude (21.3 p.p.b. to 11.9 p.p.b., p=0.03) with no further change in January (12.5 p.p.b.) or June (13.2 p.p.b.). No correlation found between eNO and lung volumes.		

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
<p>Arshad et al. Primary prevention of asthma and atopy during childhood by allergen avoidance in infancy: a randomised controlled study. Thorax 2003;58(6):489-493. (National Health Service, Research &amp; Development, South and East Region, United Kingdom)</p>	<p>Randomized, single blind, control group design (recruited and randomized antenatally)</p>	<p>To test hypothesis that in infants genetically predisposed to atopy, allergen exposure in infancy plays a critical role in the development of phenotypic manifestations</p>	<p>120 (120)</p>	<p><b>Age</b> Mean = 8.5 yr (recruited at birth; measured at 8 years of age) <b>Gender</b> 51% male, 49% female <b>Ethnicity</b> Not reported</p>	<p>Infants at high risk of developing atopy: <math>\geq 2</math> members of immediate family with allergic disorder or either parent/sibling affected with allergic disorder plus cord serum IgE <math>&gt;0.5</math> kU/L in the infant.</p>	<p><b>Arm 1</b> Prophylactic (E) Reduced allergen exposure from birth (mother on a low-allergen diet or infant given extensively hydrolyzed formula; acaricide and mattress covers) (n=58) <b>Arm 2</b> Control (C) Standard advice given by health visitors (n=62)</p>	<p>9 months; assessment at 1, 2, 4, and 8 years of age (8-year data reported here)</p>		<p>FEV<sub>1</sub> % pred. and PEF % pred., lower in E than P, but not significant.</p>	<p>*Current wheeze lower for E than C (13.8% vs. 27.4%) but not significant (p=0.08). Period prevalence of asthma symptoms lower in E than C for nocturnal cough (OR 0.34, 95% CI 0.13 to 0.84, p=0.02). No difference in current asthma (P 9.6%, C 15.5%, p=0.40). Atopy was lower in E than C (20% vs. 46.8%, OR 0.28, 95% CI 0.12 to 0.65, p=0.003). 26.4% of E and 36.7% of C were inhalant screen positive (p=0.31).</p>	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/ Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
Halcken et al. Effect of mattress and pillow encasings on children with asthma and house dust mite allergy. J Allergy Clin Immunol 2003;111(1): 169–176. (Danish Asthma and Allergy Association; Danish Research Foundation)	Multicenter, randomized, double-blind, placebo-controlled study (block randomization stratified by age, sex, initial house-dust-mite concentration, and center)	To investigate whether polyurethane mattress and pillow encasings resulted in effective long-term control of house-dust-mite allergen levels, thereby reducing the need for asthma medication in children with asthma and house-dust-mite allergy	60 (50)	<b>Age</b> 5–15 yr <b>Gender</b> Not reported <b>Ethnicity</b> Not reported	Asthma and documented allergy to house dust-mite 93% treated with inhaled steroids mean dose = 372 mcg  PC <sub>20</sub> geometric mean = 1643 SQU/mL for treatment group and 2,507 SQU/mL for placebo group	<b>Arm 1</b> Active group (A) Mattress and pillow encasings coated with semipermeable polyurethane; encasings to remain unwashed if possible, and changes in mattress, bed, and bedroom not allowed. Recommended to wash pillows and blankets/duvets every 3 months after dust sampling and sheets and pillow cases every 2 weeks. (n=30; n=28 completers) <b>Arm 2</b> Placebo (P) Placebo mattress and pillow covers made to resemble the active treatment covers (n=30; n=22 completers)	12 months; dust sampling every 3 months.  Children treated with inhaled steroids used same product during study period; all used short-acting beta <sub>2</sub> -agonists as needed during study.	House-dust-mite concentrations in mattress varied between groups across time (p=0.038) with difference for A vs. P at 6 months (geometric mean = 3,046 vs. 9,923 ng/g dust, p=0.011) and at 12 months (geometric mean = 1,456 vs. 4,311 ng/g dust, p=0.032).  Median reduction in house-dust-mite concentration remained stable in A between 81% and 89% in contrast to reductions of between –1% and 70% in P.	For both A and P, morning and evening PEF increased after 9 and 12 months (p<0.01) and FEV <sub>1</sub> increased at every visit with no difference between groups.		Daily dose of inhaled steroids reduced by ≥100 mcg/day for 73% of A vs. 29% of P.  Dose reduced by ≥50% for 54% of A vs. 10% of P after 9 months (p<0.05) and for 73% of A vs. 24% of P after 12 months (p<0.001).  Median change was 200 mcg/day for A vs. 0 mcg/day for P (p<0.01).  No difference in use of beta <sub>2</sub> -agonists for A vs. P.
Luczynska et al. A randomized controlled trial of mite allergen-impermeable bed covers in adult mite-sensitized asthmatics. Clin Exp Allergy 2003;33(12): 1648–1653.	Randomized, double-blind, control group design (General practices and outpatient clinics in south-east London)	To assess whether the use of Allerguard allergen-impermeable bed covers, as a single intervention, resulted in an improvement in allergic disease outcomes in those patients most likely to benefit from allergen avoidance	55 (31)	<b>Age</b> 16–64 yr, mean = 36 yr <b>Gender</b> 49% male, 51% female <b>Ethnicity</b> Not reported	Diagnosis of asthma  At least 1 prescription of inhaled steroids in previous 12 months  Sensitized to: cat, 35%; dog, 43%; grass, 52%; mold, 15%  Der p1 in mattress, mean = 22.6 mcg/g  Specific IgE to house-dust mite, mean = 15.7 kU/L	<b>Arm 1</b> Active treatment (A) Microfiber allergen-proof covers for mattress, duvet, and/or any blankets and all pillows (n=30; 24 started trial; 16 completers) <b>Arm 2</b> Placebo group (P) Sham covers (n=25; 20 started trial; 17 completers)	12 months; mattress-dust sample and assessment of compliance at 6 and 12 months; peak flow diaries at 4, 8 and 12 months	No difference in Der p1 level between A (decrease 25.7 mcg/g, 95% CI 8.9 to 74.1) and P (decrease 4.5 mcg/g, 95% CI 1.8 to 11.5) at end of trial.	*No change in peak flow over time and no difference between group: mean % increase for A 0.71 (95% CI –7.20 to 8.61) vs. P (1.71 (95% CI –5.54 to 8.96); difference –1.00 (95% CI –12.0 to 10.18).	No difference in chest symptoms between A and P over trial.  No change in number of asthma attacks or quality.  Decrease in square root of quality of life for A was 0.44 (95% CI –0.25 to 1.14) and for C was 0.69 (95% CI –0.74 to 1.23), difference of A–P of –0.25 (95% CI –0.74 to 1.23).	No difference between A and P in use of medication.



Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
<p>Terreehorst et al. Evaluation of impermeable covers for bedding in patients with allergic rhinitis. N Engl J Med 2003;349(3): 237-246.</p> <p>(Netherlands Organization for Health Research and Development)</p>	<p>Multicenter, randomized, double-blind, placebo-controlled trial</p>	<p>To examine the clinical effects of mite-proof covers for the bedding of mite-sensitive patients on the symptoms and signs of allergic rhinitis</p>	<p>279 (236; 232 with complete data on primary outcome)</p>	<p><b>Age</b> 8-50 yr, mean = 26.3 yr</p> <p><b>Gender</b> 40.5% male, 59.5% female</p> <p><b>Ethnicity</b> Not reported</p> <p><b>Smoking</b> 11.7% smokers</p>	<p>Clinical history of allergic rhinitis and positive nasal allergen-provocation test with house-dust-mite allergen.</p> <p>47.4% with asthma 25% with dermatitis</p> <p>Cosensitization: 55.6% grass pollen, 38.7% tree pollen, 18.2% weed pollen, 51.1% cat allergen 58.7% dog allergen</p> <p>Eosinophil count per mm<sup>3</sup>, mean = 286</p> <p>Total IgE concentration, mean = 230 kU/liter</p> <p>House-dust-mite-specific IgE concentration, mean = 13 kU/liter</p> <p>Skin-test index for house-dust mites, mean = 0.95 biologic units</p> <p>Nasal allergen-provocation test score, mean = 18.3</p>	<p><b>Arm 1</b> Intervention group (E) Impermeable bed covers with 98% barrier, encouragement to wash and clean bedding weekly in water that was 60°C and to clean, heat, and ventilate home according to regular schedule (n=139; n=115 for analysis; n=114 with complete data on primary outcome)</p> <p><b>Arm 2</b> Control group (C) Permeable bed covers that provided 15% barrier against allergen (n=140; n=121 eligible for analysis; n=118 with complete data on primary outcome)</p>	<p>12 months</p>	<p>Change in Der p1 and Der f1 in mattress (mcg/g of dust) for E vs. C (0.31 vs. 0.82, diff 0.38, 95% CI 0.23 to 0.64, p&lt;0.001).</p> <p>No effect for Der p1 and Der f1 in bedroom-floor dust (p=0.44) or for living-room-floor dust (p=0.21).</p>		<p>*Both groups had decrease in mean score on visual-analogue scale for rhinitis (E: -9.83%, 95% CI -15.28 to -4.38, p&lt;0.001; C: -10.86%, 95% CI -16.64 to -5.09, p&lt;0.001) with no difference between groups (diff: 1.03, 95% CI -6.87 to 8.94, p=0.80).</p> <p>No difference between E and C in nasal allergen-provocation score (p=0.90) or daily symptom score (0.48).</p> <p>No modification of effects of intervention by age, smoking status, gender, cosensitization to other allergens, and characteristics of the interior of the home.</p>	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
Woodcock et al. Control of exposure to mite allergen and allergen-impermeable bed covers for adults with asthma. N Engl J Med 2003;349(3): 225–236. (United Kingdom National Health Service Research and Development Programme on Asthma Management)	Multicenter, randomized, double-blind, placebo-controlled parallel-group trial (154 general practices in the Medical Research Council's General Practice Research Framework)	To test the hypothesis that allergen-impermeable bed covers improve asthma control	1122 (1,015 with 6-month followup and 965 with diary data for Phase I; 751 entered Phase II dose-reduction phase, 932 had 12-month followup and 882 with diary data)	<b>Age</b> 18–50 yr, mean = 36.7 yr <b>Gender</b> 36% male, 64% female <b>Race</b> 98% White 2% Other <b>Smoking</b> 48% ever smoked 24% current smoker 28% never smoked	Morning PEF, mean = 413 L/min Beta-agonist use, mean = 2.84 puffs/day, mean = 1.46 puffs/night All regularly taking ICS: 80% beclomethasone (dose 50–3,200 mcg, median 400 mcg), 9% budesonide (dose 200–8,000 mcg, median 1,000 mcg), 11% fluticasone (dose doubled and subsumed under budesonide).	<b>Arm 1</b> Mattress, pillow, and quilt covers impermeable to <i>D. pteronyssinus</i> 1 (Der p1) (E). (n=560, n=507 followup at 6 months, n=480 completed 6-month diary; 369 entered Phase II dose-reduction, n=466 with 12-month followup, n=437 completed 12-month diary) <b>Arm 2</b> Nonimpermeable polyester-cotton (control) bed covers (C). (n=562, n=508 followup at 6 months, n=485 completed 6-month diary; n=382 entered Phase II, n=466 had 12-month followup, n=445 completed 12-month diary)	6 months Phase I maintained usual inhaled corticosteroid therapy + 6 months. Phase II controlled individually tailored reduction of ICS therapy (25%–50% reduction each month); 4-week run-in. Adherence: At 12 months, 5.5% of E and 2.1% of C had removed their bed covers (p=0.003).	Based on 10% sample, difference between E and C in level of exposure to mite allergen at 6 months (geometric mean = 0.58 vs. 1.71 mcg/g, p=0.01 adjusted for baseline) but not at 12 months (1.05 vs. 1.64 mcg/g, p=0.74 adjusted for baseline).	*At 6 months, no difference between E and C in morning PEF adjusting for baseline (diff –1.6 L/min, 95% CI –5.9 to 2.7, p=0.46 for all patients; –1.5 L/min, 95% CI –6.9 to 3.9 among mite-sensitive patients, p=0.59).	At end of Phase I, no difference between E and C in use of beta-agonists, symptom scores, rates of exacerbations, and quality of life scores either overall or among mite-sensitive patients.	During Phase II, 14% discontinued ICS with mean reduction of 47% of E and 48% of C among those who began Phase II.

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Duration of Active Treatment; Duration of Postintervention/Off-Treatment Followup	Taper/Decrease Steroids	Lung Function	Exacerbations/Symptoms	Other
Morgan et al. Results of a home-based environmental intervention among urban children with asthma. N Engl J Med 2004;351(11): 1068–1080. (National Institute of Allergy and Infectious Diseases, National Institute of Environmental Health Sciences, and National Center for Research Resources, National Institutes of Health)	Multisite, randomized, controlled trial (blocked randomization with a site)	To determine whether an intervention tailored to each child's sensitization and environmental risk profile could improve the symptoms of asthma and decrease the use of health care services	937 (ITT analysis with 869 end of year 1 and 821 end of year 2)	<p><b>Age</b> 5–11 yr, mean = 7.6 yr</p> <p><b>Gender</b> 62.7% male, 37.3% female</p> <p><b>Ethnicity</b> 39.6% Black 40.1% Hispanic 20.3% other</p> <p><b>Family</b> Mean = 1.7 other children in home 69.4% caretaker completed high school 75.9% with member of household employed 60.3% with household income &lt; \$15,000</p> <p><b>Environmental exposure</b> 61.6% evidence of cockroaches 48% current smokers in home 45% water or dampness in home in past 12 months 22% dog in home 17% cat in home</p>	<p>Moderate-to-severe asthma</p> <p>Maximal days with asthma-related symptoms within 2 weeks, mean = 6.0 days</p> <p>FEV<sub>1</sub> % pred. mean = 87.8</p> <p>FVC % pred. mean = 96.7</p> <p>Daily variability in PEF mean = 19.4%</p> <p>Morning PEF mean = 203.9 L/min</p> <p>Asthma-related health care use in 2 months before baseline: 51.3% with unscheduled visit to ED or clinic, 14.1% with hospitalization for asthma.</p> <p>Positive skin tests: 69% cockroach allergen, 63% dust-mite allergen, 50% mold, 44% cat allergen, 33% rodent allergen, 22% dog allergen.</p>	<p><b>Arm 1</b> Intervention group (E) 6 modules that focused on remediation of exposure to allergens and intervention activities tailored to child's skin-test-sensitization profile and environmental exposures; 5 mandatory and 2 optional home visits; allergen-impermeable covers, vacuum cleaner with high efficiency particulate air filter, air purifier in child's bedroom, and professional pest control provided. (n=469; n=444 year 1 analysis, n=407 year 2 analysis)</p> <p><b>Arm 2</b> Control group (C) Visits only for evaluation at 6-month intervals.</p>	12 months; surveys of environment and collection of dust allergens at baseline and 6, 12, 18, and 24 months.	<p>Greater % change from baseline for E vs. C in bed allergens Der f1 (–59 vs. –14, p&lt;0.001), Der p1 (–37 vs. –18, p=0.007), and Fel d1 (–28 vs. +15, p&lt;0.001) in year 1 and for Der f1 (–49 vs. –25, p=0.004) and Fel d1 (–14 vs. +30, p&lt;0.001) in year 2.</p> <p>Greater % change from baseline for E vs. C in floor allergens Bla g1 (–53 vs. –19, p&lt;0.001), Der f1 (–34 vs. –9.8, p=0.004), and Fel d1 (–14 vs. +15, p=0.02) in year 1 and in Bla g1 (–64 vs. –47, p=0.003) in year 2.</p>	No difference in FEV <sub>1</sub> % pred. at 12 months for E vs. C (87.0 vs. 87.4, p=0.69) for in FVC % pred. (97.3 vs. 98.1, p=0.48).	<p>Maximal number of days with symptoms was lower in E vs. C by 0.82 days per 2-week period in 1st year (p&lt;0.001) and by 0.60 days per 2-week period in 2nd year (p&lt;0.001). Greater reduction occurred within 2 months after randomization and was sustained for the 2 years of study.</p> <p>Unscheduled visits for asthma in year 1 were 2.22 for E and 2.57 for C (diff –0.35, p=0.04) and 1.39 for E and 1.66 for C (diff –0.26, p=0.07) in year 2.</p> <p>50% reduction in allergen levels from baseline in bedroom floor levels of Bla g1 and Der f1 in E were associated with decrease in maximal number of days with symptoms, number of hospitalizations, and number of unscheduled visits for asthma in both years (p&lt;0.05).</p>	