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House Dust Mites Avoidance and Allergic Children: A Prospective Study of a New Strategy

Evelyne Jonniaux¹ and Anne-Catherine Mailleux^{2*}¹Queen Fabiola Children's University Hospital, Brussels, Belgium²Catholic University of Louvain-La-Neuve, Belgium**Abstract**

Background: Dust mites are a frequent cause of allergic rhinitis in children. Reduction of exposure seems to be the most logical way to treat these patients even if its effectiveness is controversial.

Objective: Our aim was to investigate whether a new strategy, attracting and trapping house dust mites outside the mattresses with a new type of device can reduce the symptoms of allergic children.

Methods: In a prospective study, mattresses were treated with a new type of trapping device. The principle of the device is to attract mites outside mattresses, to take them away and to kill them without insecticides. This trapping device was given to 40 children with moderate to severe house dust-mite allergy. Inclusion criteria were a positive RAST to the house dust-mite antigen or to the allergy skin tests. Severity of symptoms was estimated after two weeks by an established score. The results were observed after two uses of the trapping device (2 weeks).

Results: All patients completed the trial. No side effects were observed. At the end of the study, a significant reduction in allergic symptoms was observed. After patients had two uses of the trapping device, significant differences were observed for the nasal congestion, sneezing, nasal itching and ocular itching. No significant difference was observed for the rhinorrhea. The percentages of patients strongly affected by their allergy (with severe or moderate symptoms) and who had mild or none symptoms after two uses of the device were 70% for the nasal congestion, 47% for the sneezing, 62% for the nasal itching, 60% for the ocular itching, and 62% for the rhinorrhea.

Conclusion: Using the trapping device, commercialized under the name of Acar'up[®], produced significant and beneficial effects on symptomatology. These results encourage proceeding on this path in the choice of the therapy for those subjects affected by respiratory allergopathy to house dust mites.

Keywords: Allergy; Pediatrics; House dust mites; Eviction

Introduction

Less than a millimeter in size, house dust mites are found worldwide, primarily in human dwellings. They are harmless, but they give rise to potent allergens associated with several diseases [1,2], notably asthma [3,4]. In European houses, the principal species is *Dermatophagoides pteronyssinus* [5,6]. House dust mites thrive in dust, which accumulates in beddings, covers, blankets, mattresses, carpets, armchairs, cushions, pillows, fabrics and all padded furniture used by humans, also in places such as in teddy bears, cushions and homes in general. As well as providing a habitat for the mites, house dust also contains their food source: shed human skin scales, which become colonized by molds, yeasts and bacteria [5,6].

Dust mites reproduce very prolifically in our modern houses. Indeed, modern houses are warmer, moister and less well-ventilated (due to energy effectiveness concerns) than they used to be, partly due to double-glazing, central heating and insulation. Consequently, dust mites are more abundant than before. These allergens are biologically functional proteins within the mites. They are mainly contained in their excrements and exuviae. Clearly, the allergenic activity is incidental, an unfortunate consequence of their ubiquity and increasing abundance in human dwellings [6].

Dust mites' allergens cause allergy symptoms [6], such as itchy watery eyes, atopic dermatitis (eczema) and linked attention-deficit/hyperactivity disorder [7], asthma [8], nasal congestion and the consequent insomnia [9], sneezing, nasal itching, ocular itching, rhinorrhea and even anaphylactic shock [10,11]. Approximately 10 to 15% of the population is allergic to mites [12,13]. An ever-growing

proportion of the populations suffer not only from allergies and asthma but also from other chronic inflammatory diseases [14]. All these symptoms are strongly associated with sensitization of inhaled allergens found in the home, and the severity of these symptoms increases with the levels of dust mite allergens [15,16]. Previous studies have shown a relationship between the exposure to HDM allergens, especially in mattresses, and the development of HDM allergy [17-20]. Moreover, a relationship between the concentration of HDM allergens and asthma symptoms and severity has also been shown [3,4].

Consequently, the reduction of allergens is a reasonable and logical strategy against allergic symptoms [11]. While reducing exposure to house dust mites is recommended in guidelines (for instance, the guidelines of American Academy of Allergy Asthma and Immunology), control measures to reduce the exposure to mites or their products seem to have no effect [21,22]. At first glance, it seems to be contradictory. Our hypothesis is that this contradiction might be explained by the relative inefficiency of some usual procedures of mite and allergens' elimination. Consequently, we consider that there is a need to improve

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sanitation and to provide further methods for efficient removal of dust mites. To be effective, we consider that such a treatment must eliminate mites from the surface and from the core of the mattresses and sofas. Moreover, it must be safe for human (and pet) health, easily applicable and, if possible, safe for the environment [23].

Our objective was to investigate whether a new strategy, attracting and trapping house dust mites outside the mattresses with a new type of device can help allergic children. The principle of the trapping device is to attract mites out of mattresses or sofas with their own pheromones [24], to take them away and to kill them without insecticides. The allergens produced by mites were eliminated by using a vacuum cleaner after the first use of the trapping device. The objective of this pilot study is to evaluate the effectiveness of the trapping device as a tool of avoidance in children with house dust-mite allergy rhinitis.

Material and Methods

Our study was done with the following characteristics: homogeneous age of a study population, sensitization to the house dust mite antigen (RAST or allergy skin test) and a very short study period of time of two weeks (to exclude seasonal variations of antigen exposure as a confounding variable).

Description of the trapping device

The principle of the trapping device was to attract mites outside mattresses, to take them away and to kill them without the insecticides. The trapping device was a medical device, commercialized under the name of Acar'up®, it was composed of a textile and a spray containing the attracting solution. For the users of the trapping device, the *modus operandi* was to put a textile on the mattress or on the sofa, to spray an attracting solution that contains aggregative pheromones [24] on the technical textile. Both the textile and the attractive solution attracted mites (unpublished data, patent in course). The textile was to be laid two hours, which was the optimal time to obtain the best results. When the attracted mites were in the textile, mites were killed when users put the textile in the washing machine with some soap (Figure 1).

The trapping device removed 80% of *D. pteronyssinus* after one use, 94% after two uses and 97% after three uses (unpublished data, patent in

course). The device did not contain any insecticide mites were killed by the washing machine. The allergens were eliminated by using a vacuum cleaner after the first use of the trapping device (Figure 1). After two or three uses of the device, as the number of mites had strongly decreased, the quantity of allergens produced was very low, thus it was no longer necessary to eliminate allergens with a vacuum.

The pilot study design: This study aiming to measure the influence of the use of the trapping design on allergic children was conducted from September to November 2013 with 40 children who had a house dust-mite allergy, as assessed by a RAST or by an allergy skin test.

These children were all 16 years old or younger and suffered from moderate to severe allergies to dust mites. All the children received the trapping device. Some additional medications were allowed (see above). No change of the medications was allowed during the study. These tests and evaluation were performed at the HUDERF unit, Queen Fabiola Children's University Hospital, Brussels, Belgium.

- Criteria of inclusion
 - Patients with allergies to dust mites who are not desensitized.
 - Informed consent form signed and dated by the patient (or their parents if a minor patient).
 - Patients (or parents) able to understand the information they need, and to validly complete the daily diary, and who agree to comply with a number of rules for processing and monitoring.
 - Diagnosis of mite allergy: must be confirmed by skin tests and/or RAST, consistent with the symptoms.
 - No acute exacerbation of allergic rhinitis at baseline.
 - The poly-sensitized patients are included.
- Criteria of exclusion
 - Desensitization to mites in course.
 - Use of oral corticosteroids in the long term.
 - Use of inhaled nasal or bronchial corticosteroid (the intermittent use during the season is permitted provided it is

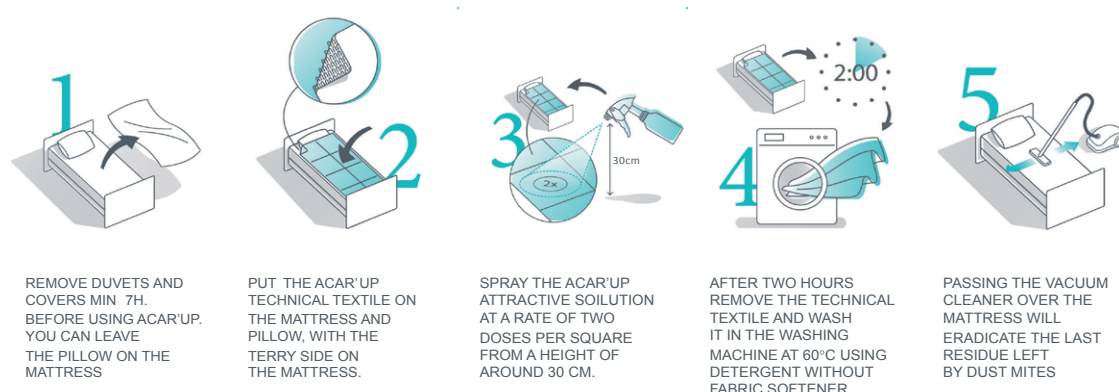


Figure 1: Instruction for use. The principle of the trapping device was to attract mites outside mattresses, to take them away and to kill them without insecticides. The trapping device was composed of a textile and a spray containing an attracting solution. The *modus operandi* was to put a textile on the mattress or on the sofa, to spray an attracting solution on the technical textile. When the attracted mites were in the textile, mites were killed when users put the textile in the washing machine with some soap. The trapping device removed 80% of *D. pteronyssinus* after one use, 94% after two uses and 97% after three uses. The device did not contain any insecticides mites were killed by the washing machine. The allergens were eliminated by using a vacuum cleaner after the first use of the trapping device.

mentioned in the book).

- Other clinically significant diseases (cardiovascular, hepatic, renal, autoimmunitaires, hematological, neurological, psychiatric, endocrine, neoplastic, etc.) that can disturb the development of the study.
- Patient intending to travel in a geographic area very different from Belgium by the end of the study.
- Patient involved in a clinical trial in the previous three months.
- The end of the study
- Each patient is free to leave the study at any time. The reason for this decision will be referred to as accurately as possible in the monitoring form (V2=end of study visit).
- The researcher, the Dr Jonniaux, may also decide at any time to exclude a patient from the study for any reason (non-exhaustive list: poor compliance, side effects or adverse effects, incident or accident, surgery, others).

The efficacy assessment

Patients had a daily dairy in which they assessed changes in the symptoms-score from D0 to D14. D0 (the baseline) was the day of the first medical visit. On this visit, some explanations were given about the trapping device and then they conducted the first use of the trapping device. On D7, they conducted the second use of the trapping device. On D14 (the end of the study), they received their second medical visits and an evaluation of the results.

The symptom assessment was based on the nasal congestion, rhinorrhea, sneezing, nasal itching and ocular itching. From D0 to D14, the subjects assessed their symptoms on a 4-point scale: 0=none; 1=mild; 2=moderate; 3=severe. The score was rated on D0 (baseline), on D7 (one week after first use) and on D14 (one week after second use).

Ethics

The study was approved by the HUDERF Ethics Committee. All the parents were given oral and written information, and the parents provided informed consent before entering the study. Patients could be withdrawn or withdraw themselves from the study at any time.

Statistical analysis

Statistical analysis was performed with Graphpad Prism software. The number of patients was 40. The 40 patients were distributed in function of the scores. In some categories, the number was lower than five. Consequently, to homogeneously analyze, we used non-parametrical tests for all data comparisons. Statistical tests were used to compare:

- a) The effectiveness based on symptoms before and after the first and second use of the trapping device. The distribution of the scores (none, mild, moderate, severe) was calculated, and the total was n=40. To illustrate the decrease of symptoms simply, we grouped the patients with severe and moderate on D0, and we grouped the patients with mild or no symptoms on D14. We calculated the differences between these two groups. This gave us the proportion of patients who were strongly affected by respiratory allergopathy and those who stopped suffering from their allergy on D14.
- b) The overall effectiveness: We added the scores of the five

observed symptoms to calculate an overall effectiveness before and after the first and second use of the trapping device. The scores (none, mild, moderate, severe) were added and the overall effectiveness represented the overall disease activity (n=200).

- c) Placebo use: According to literature (for a review on this subject, see [25]), 30% was the mean efficiency of a placebo. We compared the overall effectiveness with the distribution of the scores obtained with a theoretical placebo working with 30% effectiveness: The relative number of mild, moderate and severe scores was decreased by 30% while the relative “no symptoms” was increased by 30%.

Results

All patients completed the study. No side effects were observed.

Results by symptoms are expressed in Figure 2.

- A comparison between the distributions of the scores before and after two uses of the trapping device showed statistical differences (Figure 2). Indeed, when comparing the symptoms before and after two uses of the trapping device, we found significant differences with nasal congestion, sneezing, nasal itching and ocular itching (respectively $\chi=27.7$, $p<0.0001$; $\chi=10.51$, $p=0.01$, $\chi=14.14$; $p=0.003$, $\chi=9.40$; $p=0.04$, $DF=3$). No statistical difference was observed with the rhinorrhea, even if a trend was observable ($\chi=3.09$, $p=0.38$, $DF=3$).
- The distribution of the scores after one use of the trapping device was intermediate between the distribution before and after two uses of the trapping device. Overall, few statistical differences were found. When comparing the symptoms before and after one use of the trapping device we found significant differences with nasal congestion, nasal itching and ocular itching (respectively $\chi=22.4$, $p<0.0001$; $\chi=10.30$, $p=0.02$,

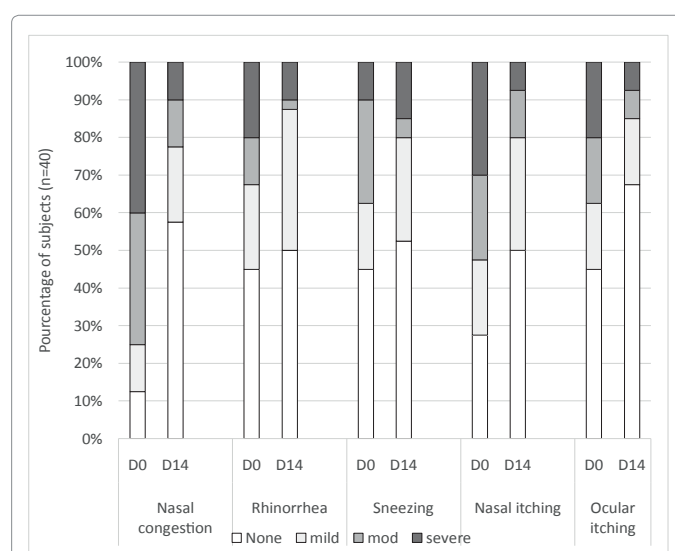


Figure 2: The % of subjects in function of the symptoms before and after two uses of the trapping device. The symptom assessment was based on the nasal congestion, rhinorrhea, sneezing, nasal itching and ocular itching. From D0 to D14, the subjects assessed their symptoms on a 4-point scale: 0=none; 1=mild; 2=moderate; 3=severe. On this figure, we represented the rated score on D0 (baseline) and on D14 (one week after second use) (for more details see the text).

$\chi=8.27$; $p=0.04$, $DF=3$). When comparing the symptoms after one use and after two uses of the trapping device, we found a significant difference with nasal congestion ($\chi=12.0$, $p<0.007$, $DF=3$). No statistical difference was observed with the other symptoms.

- Decrease of the symptoms The percentage of patients strongly affected by the allergy (with severe or moderate symptoms) on D0 and who had mild or no symptoms on D14 was 70% for the nasal congestion, 47% for the sneezing, 62% for the nasal itching, 60% for the ocular itching, 62% for the rhinorrhea (Figure 3).

Overall results

To evidence the overall effectiveness of two uses of the trapping device, we added the scores of the five symptoms. A comparison between the distributions of the scores before and after one and two uses of the trapping device showed statistical differences (Figure 3). When comparing the decrease of the symptoms after one and after two uses of the trapping device, we found significant differences (respectively $\chi=38.05$, $p<0.001$, $\chi=34.75$, $p<0.001$, $DF=3$). When comparing the symptoms after one use and after two uses of the trapping device, we found a significant difference ($\chi=27.79$, $p<0.001$, $DF=3$).

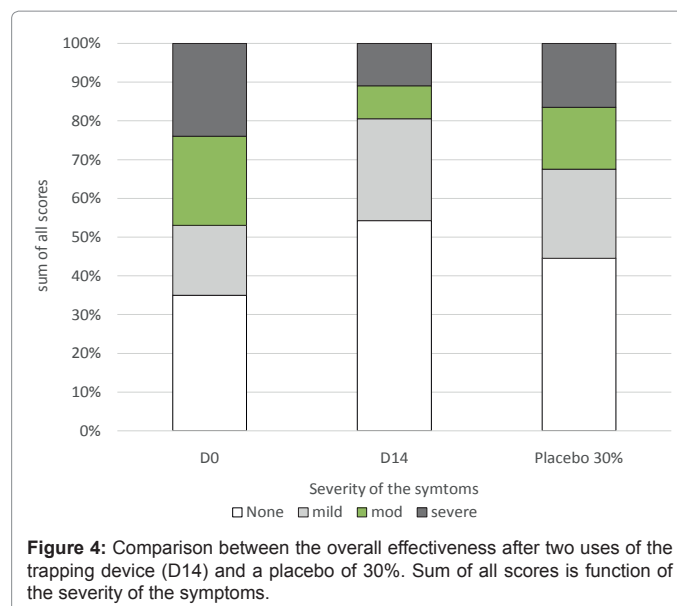
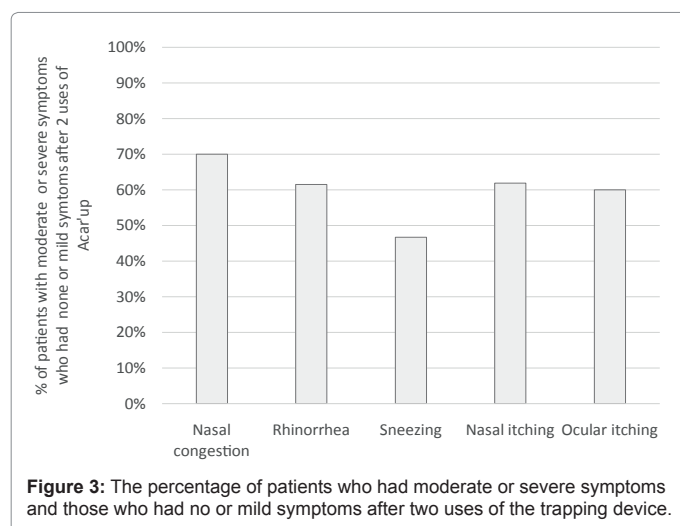
Comparison with a placebo of 30%

The relative number of mild, moderate and severe scores was decreased by 30% while the relative “no symptoms” was increased by 30%. The effectiveness of this theoretical placebo represented the improvement of the overall disease activity due to a placebo of 30% ($n=200$). When comparing the overall effectiveness after two uses of the trapping device and the theoretical placebo of 30%, we found statistical differences (respectively $\chi=23.12$, $p<0.001$; $\chi=9.31$, $p=0.002$, $DF=3$), meaning that the effectiveness of the trapping device after one and after two uses is higher than would be with a placebo, decreasing 30% of the symptoms (Figure 4).

Discussions and Conclusions

The effectiveness of the trapping device on allergy symptoms

The strategy presented here, attracting and trapping house dust mites outside the mattresses before killing them can help allergic children. No side effects were observed. After two uses of the trapping



device (two weeks) called Acar'up®, we observed significant differences for the nasal congestion, sneezing, nasal itching and ocular itching. No significant difference was observed for the rhinorrhea. One might hypothesize that this result is completely due to a placebo effect. We observed a significant difference between our results after two weeks and a placebo with an efficiency of 30%, which is the theoretical efficiency of a placebo.

This work is a prospective study. With this type of device, it is quite impossible to make a correct placebo as the technical textile and the odor of the attracting solution are easily recognizable. It is hard to change one component without changing its appearance, its odour. Therefore, a double-blind study with a placebo is unfeasible.

The device seemed to reduce the symptoms. One can imagine that the reduction of the symptoms should be improved by a longer treatment. This trap and the method of eliminating house dust mites and allergens seemed to be a useful innovation in the prevention of allergy symptoms. However, this study included only a small numbers of patients and a short follow-up period. In a future study, it would be interesting to increase the number of patients and to obtain objective metric data instead of subjective measurements such as symptoms. We should also compare the effectiveness of the trapping device and the encasements.

The trapping device removes 80% of *D. pteronyssinus* after one use, 94% after two utilizations and 97% after three utilizations. From an epidemiology point of view, this fact is not a disadvantage. One of the most plausible explanations for the increase of the prevalence of allergic diseases [26] is the “hygiene hypothesis,” which suggests that a decreased or an altered exposure to microbes in early childhood results in alteration of immunoregulation [27,28]. In this context, it might be better to keep a small population of mites in the bed to avoid such a decrease of exposure. Indeed, if a decrease of 80% of mites and related allergens is sufficient to help the patients; a total elimination of dust mites is not required. From a hygienic point of view, the fact that the trapping device removes 80% of *D. pteronyssinus* after one use is not a disadvantage. Mites eat skin flakes and organic matter, all things that can be media for the development of *Aspergillus spp.*, a fungus responsible for pneumonia. Therefore, the remaining population of

dust mites that has not been trapped by the trapping device can have a positive role by cleaning the mattresses. If a decrease of 80% of mites is not sufficient for some of the patients, they only need use it a second time or until the allergens produced by the remaining mites are below the threshold triggering the symptoms.

The controversy on eviction of house dust mites

There is only limited evidence that eliminating house dust mites reduces the severity of allergic symptoms. Some authors observed a significant clinical improvement [29]. Other studies did not demonstrate a correlation between the elimination of mites and an improvement of the clinical score. Recent meta-analysis [22] showed that chemical and physical methods aimed at reducing exposure to house dust-mite allergens does not have any effect on clinical outcomes in people with allergies known to be sensitive to house dust mites. At first glance, it seems a paradox that house-dust mites are found in indoor dust samples but avoidance measures do not have any effect.

About eviction, one thing must be highlight: Killing dust mites is not the same as allergen avoidance, some studies mixed these two concepts and used it as synonymous. One could kill every mite in a home, but unless the allergens are removed, the allergenic load and exposure risk remains the same. If one removes allergens without killing mites, the allergen load may decrease temporarily, but will then build up again as mites grow, reproduce and defecate [6]. Substantial reductions in mite population density and allergen concentrations are likely to be necessary if a lasting clinical benefit is to be achieved. This means a combination of acaricidal methods (the trap) and thorough vacuuming the allergens.

The protocols of many studies were objectionable;

1) To get rid of mites and the allergens that they produce, various sanitation methods have been proposed [30,31]. Therefore, in field study measuring eviction efficiency, the most common and simple way of removing dust mites was vacuuming. This method removes allergens efficiently if cleaners contain a good HEPA filter. Vacuums do not remove or kill dust mites, however. Indeed, dust mites cling on to fabric fibers, making them very difficult to remove. Therefore, vacuum cleaners can be regarded only as a product to eliminate allergens and an adjunct to methods that kill mites. Moreover, mattresses usually have a considerable thickness, such that either vacuuming or the application of pesticides may only result in superficial treatment [6]. As dust mites may reside in the core of the mattress or sofas, such superficial treatment often proves not to be very efficacious [6]. Cleaning only with a vacuum is not sufficient.

2) Another usual tool to reduce mites in field study is encasing mattresses and pillows [32,33]. Gutgesell et al.'s study [34] results showed that for adult patients with atopic dermatitis, one year of house dust-mite avoidance reduced the allergen exposure, but an improvement of overall disease activity was not demonstrated. One possible hypothesis for this lack of improvement is that concentrating on bed coverings may omit treatment of mites elsewhere in the home environment. As people spend more and more time sitting and sleeping in their sofas, the encasing is insufficient. Sofas' should be cleaned too. Moreover encasing's textiles suffer from the friction of the body during sleep and from the acidity of the perspiration and sweat. Consequently, these encasing might not stay impermeable to all house dust mites and/or to the allergens that they produce. When one sleeps on an encasing, the perspiration is not absorbed by the mattress, which increases the local humidity in the beds of allergic people and the proliferation of mites is thus favored.

3) Another way of dealing with mites' infestations in field studies consisted in the application of synthetic pesticides. Pesticide compounds are commonly added to fabrics and textiles during the manufacture of mattresses, pillows, carpets and clothing [6]. These compounds are widely used, even though the consumer may not know or be only faintly aware. The effectiveness of the used pesticides is questionable as mites seem to develop a resistance to them.

4) In several studies, the 'placebo' treatments or dust sampling protocols could have had a significant effect in reducing allergen levels.

5) In most cases, either the reduction in allergen levels in the active groups was too small or, if it was large, so was the fall in allergen levels in the control group.

6) The allergens were not efficiently measured: Trials invariably used dust sampling from the upper surface of the mattress or floor. A better approach would be to compare direct measures of exposure like airborne sampling at the beginning and end of the trial, and use of a less indirect measure of exposure.

7) The effect of patients undertaking parts of the intervention (e.g. vacuum cleaning, applying acaricides) reduces standardization. In many studies, patients or their families respond to the increased attention they receive from their enrolment in a clinical trial by improving their performance (at mite and allergen control measures), regardless of whether they are in the control or intervention group [35].

In conclusions, the clinical and field studies does not show that reducing mite exposure does not improve asthma or other allergic symptoms. There is ample evidence that reducing mite exposure can and does improve asthma, eczema, rhino conjunctivitis, particularly from trials on removing patients to low allergen (for a review see 6). The interventions designed to reduce dust-mite exposure should be more efficient with a trapping device such as our trap Acar'up®.

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TESTS D'EFFICACITÉ INSECTICIDES *depuis 1986* INSECTICIDE BIOASSAYS *SINCE 1986*

QUALITY CONTROL

Report n° 2260-TCT43bis-Lot 4018722 (Exp 06/20)

Type of trial : TRAPPING COVER TEST – On a standard 100 g/m² white 100% cotton bed sheet

Protocol: Dr Mailleux' methodology with the following deviation: instead of using a Berlese system, the experimenter retrieved the mites in the cover (Acar'up standard grey cover) by exposing it on a heating plate at 40°C during 30 minutes (Bischoff's method, as described in the NF G 39011 standard), so the mites will go up and will be stucked on a black sticky paper placed on the top of the device. Counts were done 1 hour after the treatment and the exposure of the cover onto the infested simulated mattress.

Note : the simulated mattress was 3 months preinfested

Sample: « Acar'up » Batch 4018722 40019934 – Exp: 06/20 – Sample received the 11.05.2020 from "PURNA". Trial on 1 container ("Midden").

Summary of results (the raw data are in Appendix).

Treatment on the cover	% of mites on the cover after 1 hour
Nothing	1.3
Water	3.2
Test sample	86.6

The counts in the serie without treatment and treated with water validated the trial.

CONCLUSION

In the conditions of this trial, with the provided sample, the mites' strain and the methodology used,

the sample « Acar'up Batch 4018722 40019934 Exp:06/20, has proved a 87% efficacy effect towards the house dust mite *Dermatophagoides pteronyssinus*.

Work performed for:

Acar'Up SPRL

Clos Chapelle aux Champs 30

B – 1200 Brussels - BELGIUM

MAY 2020

Report n° 2260-TCT43bis-Batch4018722 Exp0620/0917R

AGRÈMENT
ESSAIS OFFICIELLEMENT
RECONNUS
N° 94-0021

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RAW DATA

% of mites on the cover after 1 hour

Treatment on the cover	Replicate	Container 1			Mean
Test sample	1	86			86,0
	2	85			85,0
	3	87			87,0
	4	87			87,0
	5	84			84,0
	6	81			81,0
	7	86			86,0
	8	89			89,0
	9	90			90,0
	10	91			91,0
	mean	86,6			86,6

Treatment on the cover	Replicate	% of mites on the cover after 1 hour
Nothing	1	0
	2	2
	3	2
	4	2
	5	4
	6	1
	7	0
	8	0
	9	1
	10	1
	mean	1,3
Water	1	3
	2	2
	3	2
	4	2
	5	3
	6	4
	7	4
	8	5
	9	5
	10	2
	mean	3,2