

## EVIDENCE-BASED HEALTH CARE

### BEDDING COVERS FOR PEOPLE WITH ALLERGIC RHINITIS

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#### Background

A patient comes to you asking whether using a mattress cover would help her allergic rhinitis. You know that she is allergic to house-dust mites and you know also that bedding covers have been widely recommended for allergic rhinitis, not least by several clinical guidelines.<sup>1,2</sup> You have also heard however that some doubt has been cast on the evidence supporting these recommendations. With your interest raised, you determine to try to find out for yourself...

#### So what is the question?

To get the right answer one first needs the right question. One question might be: 'In people with allergic rhinitis, what is the effect of impermeable bedding covers on the symptoms of allergic rhinitis?'

#### The type of evidence to look for, and where to look for it

Treatments are best assessed by randomised controlled trials.\* If more than one trial has been performed, the best evidence, if available, will usually come from a systematic review\* of the valid randomised controlled trials. Next best would be the randomised controlled trials themselves. If they do not exist, one must rely on less rigorous sources of evidence, and make allowance for the loss of rigour. In a so-called 'hierarchy of evidence', the next-best sources of evidence on interventions are usually, in order, non-randomised controlled trials, case-control studies, case reports or case series, and expert opinion.

For an intervention, a first port of call would be the Cochrane Library.\* A next option is the 'Clinical Queries' feature of Pubmed. This feature automatically uses specially designed search strategies to filter out the 'hits' most likely to answer clinical questions about therapy, or diagnosis, or aetiology or prognosis. It is

#### Aims

This feature on evidence-based health care aims to present useful practice-related information on topics relevant to readers of *Current Allergy & Clinical Immunology*. The treatment of each topic is not comprehensive. The main aim is to illustrate selected aspects of the process of i) getting the evidence straight and ii) applying valid evidence to practice. The box entitled 'Some terms explained' enlarges on the technical terms mentioned in the text and marked with an asterisk (\*).

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also possible to search for systematic reviews on your topic of interest.

#### What was found

A Cochrane review does exist, which found that: 'Trials to date have been small and of poor methodological quality making it difficult to offer definitive recommendations...'<sup>3</sup> (unfortunately not an uncommon finding). However, this was last updated in February 2003.

Maybe something useful had been published since then? A next step would be to search PubMed, using the 'Clinical Queries' option you see in the left-hand column of the PubMed webpage (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>). Choosing the 'Find Systematic Reviews' box, and typing in 'allergic rhinitis AND covers', two reviews were identified. One was the Cochrane review.<sup>3</sup> The other came from a prestigious institution and was even available on-line.<sup>4</sup> This review however appeared not to be systematic. The abstract said it was a 'critical review' rather than a systematic one, and mentioned no methods of the review (a rough rule of thumb is that true systematic reviews have methods sections, even in the abstract). The article also cost \$30. Next port of call was the 'Search by Clinical Study Category' in 'Clinical Queries'. Typing in the same search terms, clicking on 'therapy' to describe the kind of information you were after, and choosing a 'narrow specific search', four 'hits' popped up. One from July 2003 dealt specifically with bedding covers and allergic rhinitis.<sup>5</sup>

#### What the authors did

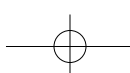
A randomised controlled trial of 279 patients (average age 26 years) with allergic rhinitis and house-dust mite sensitisation who received either impermeable covers for mattress, pillows and duvet or blanket, or identical (except non-permeable) control covers. The primary outcome of the trial was a change in a rhinitis symptom score (out of 100) after 12 months.

#### Results

Outcome	Bedding covers	Control
Rhinitis-specific symptom score (/100)		
At baseline	52.2	49.8
After 12 months	42.3	39.0
Mean improvement (with 95% confidence interval)	9.8 (4.4 to 15.3)	10.9 (5.1 to 16.7)
Difference between improvements	-1.0 (-8.9 to 6.9)	

#### Other findings

- There was a significant reduction in house-dust mite concentrations in the mattresses of the impermeable-cover group, and this was not seen in the control group.
- No subgroups of patients were identified in whom the intervention worked differently.



### Some comments

- The bedding covers succeeded in reducing house-dust mite concentrations but did not improve symptoms. Beware of research that uses intermediate or 'surrogate' outcomes, such as laboratory results or mite counts, rather than clinically meaningful outcomes such as symptoms. One has to assume that the 'surrogate' outcome actually represents improved health. This study illustrates that this is not necessarily true.
- The point estimate ('best guess') from this study is that there was a difference in symptom scores of one point in favour of the control. However, the 95% confidence interval indicates that the true size of the difference (which is never exactly known) has a 95% chance of falling somewhere between a score of 8.9 points less to 6.9 points more for the bedding group. Thus, if an improvement of less than seven points could still be a meaningful improvement, then this study does not exclude a meaningful effect. Neither does it exclude meaningful harm. Remember that lack of evidence of an effect is not the same as evidence of no effect.
- The symptom score actually improved by 9.8 points during the trial, which was statistically highly significant\* ( $p < 0.001$ ). However, the control group improved even more, by 10.9 points. Something else was happening during the course of the trial that

resulted in improvement and had nothing to do with bedding covers (probably a phenomenon called regression to the mean, but you won't want to know about that). The point is that, if a control group had not been used to see what happened without the intervention, it would probably have been falsely concluded that bedding covers are effective. Beware of uncontrolled 'before-after' studies.

- When the Cochrane systematic review is next updated, it will most likely include the trial featured here, and any other valid new trials that we might have missed in our quick search.

### References

1. Van Cauwenberge P, Bachert C, Passalacqua G, *et al.* Consensus statement on the treatment of allergic rhinitis. European Academy of Allergology and Clinical Immunology. *Allergy* 2000; **55**: 116-134.
2. International Consensus Report on the diagnosis and management of rhinitis. International Rhinitis Management Working Group. *Allergy* 1994; **49** (19 Suppl): 1-34.
3. Sheikh A, Hurwitz B. House dust mite avoidance measures for perennial allergic rhinitis. *The Cochrane Database of Systematic Reviews* 2001, Issue 4. Art. No.: CD001563. DOI: 10.1002/14651858.CD001563
4. Sanico AM. Latest developments in the management of allergic rhinitis. *Clin Rev Allergy Immunol* 2004; **27**: 181-189.
5. Terreehorst I, Hak E, Oosting AJ, *et al.* Evaluation of impermeable covers for bedding in patients with allergic rhinitis. *N Engl J Med* 2003; **349**: 237-246.

### \*Some terms explained

**Cochrane Library.** An electronic collection of over 2 000 high-quality systematic reviews, it is a good first port of call when looking for evidence on interventions. In South Africa the Cochrane Library is accessible (after registering) free of charge at <http://www.sahealthinfo.org/evidence/databases.htm>

**Randomised controlled trial.** In a controlled trial patients are actively allocated to either receive treatment or be in a control group. The control group allows comparison of the outcome with treatment and the outcome without treatment. However the two groups need to be as similar as possible before the trial starts, so that any differences at the end can be attributed to the treatment. Randomly allocating participants to treatment or control is the best way we know of obtaining groups that are comparable.

**Statistical significance, p values.** The p value is the probability that the observed or greater difference between groups has occurred by chance, if there were in fact no real difference. If this probability is less than 1/20 (a p value of less than 0.05), we would conventionally accept that the finding is

not due to chance, i.e. 'statistically significant'. This cut-off of 0.05 is entirely arbitrary. Because chance variation has a greater influence on the findings of smaller studies, the p value is affected by the sample size. In this study the symptom score in the impermeable cover group actually improved by 9.8 points during the trial, which was statistically highly significant ( $p < 0.001$ ), i.e. less than one chance in 1 000 that the finding was due to chance. The difference is highly unlikely to be due to chance, but it is not necessarily due to the covers, as is seen in this trial (an even greater improvement occurred in the control group).

**Systematic review.** This is a literature review conducted itself like a research study, in order to minimise the many unintended (and sometimes subtle) biases that can creep into traditional literature reviews. It uses specified systematic methods to identify, appraise and summarise studies aimed at answering a defined question. A Cochrane review is a systematic review performed under the auspices of an international collaboration called the Cochrane Collaboration. There are however many systematic reviews performed outside of the Cochrane Collaboration.