Intervention study to evaluate the importance of information given to patients with contact allergy: a randomized, investigator-blinded clinical trial*

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Linked Comment: Korkmaz and Boyvat. Br J Dermatol 2021; 184:2.

Summary

Background In contact dermatitis, it is crucial to understand and remember the outcome of patch testing. Unfortunately, many patients do not remember the results of their patch tests.

Objectives Our aim was to evaluate the effects of an intervention programme in which extensive information on specific contact allergy was provided, in individuals with positive patch test reactions.

Methods The study was designed as a randomized, investigator-blinded clinical trial. Participants with positive test reactions were randomized into two groups that received either standard information according to clinical routine or standard information and a reminder letter. Knowledge of contact allergies was evaluated using questionnaires 12 months after inclusion.

Results There were 184 adults included in the trial and the response rate at 1-year follow-up was 78% (143 of 184). Sixty-five per cent (45 of 69) in the intervention group and 54% (40 of 74) in the control group reported the correct name of the allergen (P = 0.23). Participants with several – as opposed to few – positive patch test reactions had difficulty in remembering the correct names of the allergens (P = 0.001). Moreover, the type of allergy had an influence on their ability to remember the name of the allergen correctly and their ability to make changes in lifestyle.

Conclusions The intervention performed did not significantly affect the participants’ ability to remember their contact allergy. To achieve better knowledge and changes in lifestyle, efforts to inform should concentrate on individuals with several positive patch test reactions, those with particular allergens, individuals over 60 years of age, and – concerning changes in lifestyle – males.

What is already known about this topic?
• Patch testing is crucial for patients with contact dermatitis.
• The ability to remember and understand the outcome of the patch testing is fundamental.
• Unfortunately, many patients do not remember or have misunderstood the results of their patch tests. Patients who require more information should be identified.

What does this study add?
• This study suggests that participants’ ability to remember and understand their patch test results, and also to make changes in lifestyle, are dependent on factors such as the number of contact allergies, which allergy they have, age and sex.
Contact dermatitis (CD) can cause a chronic recurrent therapy-resistant skin disease such as hand eczema, and may affect an individual’s daily life and work ability.\textsuperscript{1–3} CD has a considerable prevalence,\textsuperscript{4,5} and more than one-quarter of the European population was found to show contact allergy to at least one allergen in the European baseline series.\textsuperscript{6} Moreover, CD is a well-known public health problem causing high costs to society.\textsuperscript{1,7,8}

However, studies have shown that patients are poor at recalling and avoiding the relevant allergen(s). Jamil et al. found that after 1–10 years, 79% remembered a positive test result and only 29% remembered the correct name of the allergen.\textsuperscript{9} In another study, 13% of patients did not remember their occupational contact allergy to rubber chemicals or epoxy after 2 years.\textsuperscript{10} Moreover, if there was an additional contact allergy, fewer than 36% remembered this correctly.

It is essential that patients remember their test results and use this information to avoid contact with the relevant allergen(s). Unfortunately, this is not always the case and individuals who need additional or repeated information about the allergen should be identified.\textsuperscript{10}

A recent study has failed to show any significant effects of an educational intervention and skin care programme on severity, quality of life and sickness absence in patients with hand eczema.\textsuperscript{11} However, a positive influence on knowledge and behaviour regarding skin care and protection of hand eczema was reported by the intervention group of the clinical trial.\textsuperscript{11}

Very little is known about the impact of the information given – concerning the allergen causing the positive patch test reaction, severity and treatment outcomes, effect on quality of life, and how to avoid the relevant allergen in daily life – on individuals with contact allergy.

The aim of the present study was to determine whether additional test outcome information given to individuals with a positive test result would improve their knowledge of the diagnosed contact allergy and therefore their ability to make changes in lifestyle.

Materials and methods

Study population

From November 2013 to May 2016 a total of 396 participants, aged ≥ 18 years, were included in the study. The participants were recruited from the Department of Dermatology and Venereology, Lund University Hospital, and all individuals suffered from dermatitis and were suspected of having allergic CD. The study was registered at ClinicalTrials.gov (identifier: NCT01953380).

Patch testing

The participants were subsequently patch tested with Mekostest, panels I and II (Mekos AS, Hillerod, Denmark), and additional test preparations from Chemotechnique MB Diagnostics AB (Vellinge, Sweden) were applied with Finn chambers, diameter 8 mm (Navamedic, Göteborg, Sweden), to meet the Swedish baseline series criteria of 2014. Tests were applied on the back of the participant and occluded for 2 days. Patch testing was performed according to guidelines,\textsuperscript{12} and a 1+, 2+ or 3+ skin reaction on day 3 and/or day 7 was documented as a positive reaction.

Questionnaire

Before patch testing, the participants filled out questionnaires, based on the Nordic Occupational Skin Questionnaire (NOSQ-2002/Long).\textsuperscript{13} The same questionnaire was sent to all the participants at 1-year follow-up, with additional questions shown in Table 1. These four questions are included in this study (Table 1 and Table S1; see Supporting Information). The participants’ answers to the questionnaires were compared with the results of the patch test readings done by the dermatologist. The individuals’ opinion of the severity of their dermatitis was marked in a numerical rating scale (NRS); left end at 0 (no symptoms) and right end at 10 (very severe symptoms).

The participants gave informed consent complying with the Helsinki Declaration, and the study was approved by the Regional Ethics Examination Board of Lund, Sweden (entry no. 100/2013).

Randomization and intervention

Forty-six per cent (184 of 396) of the participants were diagnosed with a minimum of one positive patch test reaction from the Swedish baseline series and were randomized into two groups. One group received standard information according to clinical routine, i.e. information given orally and in writing, about the allergen causing the positive patch test reaction, encountering the allergen, and avoidance. The intervention group received the standard information as above, and also a reminder letter after 3 months, giving standardized information in written form (the Swedish Society for
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Table 1 Questions to the participants at the 1-year follow-up and evaluations of the answers

| # | Question Assessment |  |
|---|---------------------|---|
| 1 | ‘Have you been tested for any skin allergies?’ | ‘Yes’ and ‘patch tested’ had to be marked to be considered as a correct answer |
| 2 | ‘Have you tested positive for any of the following allergens?’ | The patient had to answer correctly regarding which allergy/allergies he/she had; otherwise the answer was considered to be incorrect |
| 3 | ‘Do you know where the allergen occurs?’ | The answers were assessed by a specialist in dermatology and if they were considered to be reasonable (i.e. the patient knew where the allergen can be found, in what products, etc.), they were considered to be correct. If the answer was ‘no’ or obviously wrong, the question was considered to have been incorrectly answered (missing data: n = 3) |
| 4 | ‘Have you changed something in your life due to the results of the patch test?’ | These answers were assessed and if they were considered to be reasonable, they were counted as correct. If ‘no’ or obviously wrong, the question was considered to have been incorrectly answered (missing data: n = 2) |

Dermatology and Venereology, https://www.ssdv.se/svenska-s Mellskapet-för-arbets-och-miljödermatologi-ssamd/radlappa r) about the allergen causing the positive patch test reaction, encountering the allergen, and avoidance. The follow-up questionnaire was sent out to both groups after 12 months (Figure 1). The randomization was stratified according to sex. The investigators were blinded regarding the intervention throughout the study.

Statistics

Fisher’s exact test and \( \chi^2 \) tests were used to evaluate differences between the groups. A multiple regression model was used to explain the relationship between the variables and calculate odds ratios; adjustments were done for age, sex, severity of eczema and allergens. Analyses were performed using Stata 14 (2015; StataCorp LLC, College Station, TX, USA) and \( P\)-values less than 0.05 were considered to be statistically significant. In the calculations of sample size, we predicted 50% correct answers in the control group and 75% correct answers in the intervention group. This estimated 50% improvement in knowledge gave a targeted sample size of 58 participants in each group (\( \alpha = 0.05, \beta = 0.2, \) and power = 0.8).

Results

Characteristics of participants

A total of 184 individuals tested positive for one or more allergens and they were randomized into the intervention and control groups. At the 1-year follow-up, the response rate was 78% (143 of 184), and there was no significant difference between the female response rate (78%, 111 of 142) and the male response rate (76%, 32 of 42). One individual was included by mistake and randomized. The participant did not fulfill the inclusion criteria (was not patch tested for the baseline series) and was later excluded. The total response rate was 75% (69 of 92) in the intervention group and 80% (74 of 92) in the control group (Figure 1). The characteristics and a comparison of responders and dropouts are presented in Table 2.

Remembering diagnosed contact allergies

Among the responders to the follow-up questionnaire, 94% (65 of 69) in the intervention group and 97% (72 of 74) in the control group reported that they had been tested for contact allergy (\( P = 0.43 \)). Sixty-five per cent (45 of 69) of the participants in the intervention group and 54% (40 of 74) in the control group gave the correct name of the allergen (\( P = 0.23 \)) (Table 3). Moreover, a multiple regression model was performed to illustrate the relationship between the variables (Table S2; see Supporting Information). No differences concerning self-evaluation of severity of dermatitis, using NRS, was found between the groups (Table 3).

When we analysed the ability to correctly remember positive patch test reactions among all participants in both the intervention and control groups, 68% (70 of 103) with a positive patch test reaction to one or two allergens remembered correctly, whereas the corresponding figure for participants with three or more positive patch test reactions was 38% (15 of 40) (\( P = 0.001 \)) (Table S3a; see Supporting Information). Furthermore, as shown by the results of the multiple regression model, participants with few positive patch test reactions (one or two allergens) were four times more likely to remember correctly, compared with those with three or more reactions (Table S3b; see Supporting Information).

Among the participants in this study, the three most frequent positive patch test reactions were to metals, preservatives and perfumes. Participants with metal allergies only gave the correct name in 88% (28 of 32). The corresponding figure for preservatives was 58% (14 of 24), and it was 50% (3 of 6) for perfume (\( P = 0.023 \)) (Table S4a; see Supporting Information). The ease of remembering allergy to metal was confirmed by the multiple regression model (Table S4b; see Supporting Information).
Differences in knowledge of where or in what products the contact allergen occurred

Regarding knowledge of where or in what products the allergen occurred, 60% (40 of 67) of the respondents in the intervention group gave adequate answers about the allergen; the corresponding figure for the control group was 53% (39 of 73) ($P = 0.5$). Among all participants, individuals under 40 years of age reported correctly in 73% of cases (35 of 48). For individuals aged 40–60 years, the corresponding figure was 52% (28 of 54) and for participants over 60 years, it was 42% (16 of 38) ($P = 0.012$). When the answers from all participants regarding knowledge of where or in what products the allergen occurred were evaluated, a significant difference was found between men (41%, 13 of 32) and women (61%, 66 of 108) ($P = 0.045$). As shown by the multiple regression analysis, giving adequate answers was 75% less likely if the participant was 60 years of age or older, compared with those under 40 years (Table S5; see Supporting Information).

Changes in lifestyle as a consequence of the patch test result

Fifty-nine per cent (41 of 69) of the respondents in the intervention group and 46% (34 of 74) of those in the control group reported that they had made changes in their lifestyle

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**Table 2** Characteristics of the participants. Comparison of the responders and the dropouts

|                        | Responders | Dropouts |
|------------------------|------------|----------|
| **N**                  |            |          |
| Total                  | 184        | 41 (22)  |
| Sex                    |            |          |
| Female                 | 142        | 31 (22)  |
| Male                   | 42         | 10 (24)  |
| Median age, years (IQR)|            |          |
| Total                  | 49 (26)    | 37 (25)  |
| Female                 | 47 (27)    | 43 (29)  |
| Male                   | 51-5 (23)  | 30-5 (21)|

IQR, interquartile range.
as a consequence of the patch test result \( (P = 0.13) \). When the ability to make changes in lifestyle was compared between all the participants, a significantly larger proportion of the women had made changes to their lifestyle: 60% of women (65 of 109) as opposed to 38% of men (12 of 32) \( (P = 0.04) \). No significant differences were found between participants in different age groups (Table 4 and Table S6; see Supporting Information). In participants with a positive patch test reaction to only one allergen (metals, preservatives or perfumes), there was a significant difference in the reported ability to make changes to their lifestyle (Table 5), individuals with reaction to preservatives or perfumes were 12 times more likely to make changes in lifestyle compared with participants with reactions to a metal (Table S6; see Supporting Information).

### Discussion

In this study we evaluated the effects of an intervention programme consisting of written information about the contact allergy, which was sent to the participants as a reminder letter 3 months after patch testing. However, the intervention did not result in significantly higher ability to recall the name of the contact allergen compared with standard information. Limitations of the study were the small sample size, and that when designing the study, we overestimated the expected effects of improvement in knowledge resulting from the intervention programme. However, as the study was conducted at a single site we were limited in our ability to increase the sample size. In this study the proportion of women was higher than the proportion of men; however, the prevalence of contact allergy was previously reported to be higher in women,\(^6\) and this must be considered when the results are interpreted. Furthermore, we have no data on whether the participants were seen by other physicians, such as general practitioners, or if they had been tested further with the Swedish baseline series, during the 12-month period. The education level of the participants was not analysed, which would be an interesting factor to consider in future intervention studies. However, even though data indicate an association of higher education with better ability to recall allergens,\(^14\) a recent report failed to show any effect of educational background on allergen recollection.\(^15\) Moreover, concerning skin protection, data showing an inverse correlation between high educational level and knowledge of skin protection has recently been published.\(^16\)

There have been previous studies, carried out by others, on educational programmes in the prevention of hand eczema.\(^11,17\) Even though prevention programmes have shown positive results, as reported at short-term follow-up, there have been suggestions about repeating the education at regular intervals to gain positive effects in the long term.\(^18,19\) Even though we could not prove a significant effect of the intervention used in this study, it seems reasonable to assume that repeated education and information given to patients would result in better knowledge of the contact allergy and changes

### Table 3

Comparison of the control and intervention groups concerning the ability to recall the correct name of the allergen. The proportion of participants who gave the correct answer are given.

|       | Control group | Intervention group | P-value |
|-------|---------------|--------------------|---------|
|       | N             | n/total n (%)      |         |
| Total | 143           | 40/74 (54)         | 45/69 (65) | 0.23 |
| Sex   |               |                    |         |
| Female| 111           | 33/58 (57)         | 36/53 (68) |       |
| Male  | 32            | 7/16 (44)          | 9/16 (56)  |       |
| Age (years) |         |                    |         |
| Under 40 | 49           | 10/23 (43)        | 16/26 (62) |       |
| 40–60      | 54            | 22/32 (69)       | 12/22 (55)  |       |
| Over 60   | 40            | 8/19 (42)         | 17/21 (81)  |       |
| NRS, median score (IQR) |         |                    |         |
| At baseline: | 3 (4)        | 3–5 (4)           | 0.95    |
|          | [n = 72]     |                    |         |
| After intervention | 3–5 (5)  | 3 (3–5)          |         |
|          | [n = 50]     |                    |         |

IQR, interquartile range.

### Table 4

Comparison of participants, in different age groups and with positive patch test reactions to few (one or two) or multiple (three or more) allergens, and the ability to make changes to their lifestyle

| Age (years) | N         | % (P-value) |
|------------|-----------|-------------|
| Under 40   | 49        | 19 (39) (0.53) |
| 40–60      | 53        | 26 (49) (0.51) |
| Over 60    | 39        | 19 (49) (0.51) |

### Table 5

Comparison of participants with one positive patch test reaction to a metal, preservative or perfume, and their ability to make changes to their lifestyle

| Type of allergen | N | % (P-value) |
|-----------------|---|-------------|
| Metal           | 32| 24 (75) (< 0.001) |
| Preservative    | 23| 7 (30) (0.70)  |
| Perfume         | 6 | 0 (0) (1.00)   |
in lifestyle, including avoidance of the allergen. Moreover, a previous report has revealed a correlation between clearance of the eczema and the use of an information list by individuals with contact allergy. Other studies determining the value of patch testing and the effectiveness of advice given revealed that 72% of individuals with diagnosed allergic CD believed that they were helped by the patch testing, and that written information appears to be less well understood than verbal information, which highlights the importance of education given verbally to patients with CD. However, exactly how this information should be provided to gain the best effect should be investigated further.

There was apparently a tendency to have a better outcome from the intervention in participants over 60 years of age concerning the ability to correctly recall the names of contact allergies (Table 3). In addition, compared with younger participants, participants over 60 years gave correct answers to a significantly lower degree regarding their knowledge of where or in what products the allergen occurred. Furthermore, compared with patients with only one or two positive patch test reactions, patients with multiple positive patch test reactions appeared to have difficulty in recalling the correct names of the allergens (Table S3 (a, b); see Supporting Information), which is consistent with previous published data. This result is interesting, as a recently published report identified multiple allergen positivity as a poor prognostic factor in patients with CD. Moreover, it has been reported previously that the ease of remembering the names of allergies tends to vary, perhaps because it is difficult to remember complicated chemical names. However, in the present study the results showed variation in the proportions of participants with allergy to metals, preservatives and perfumes, in the ability to remember the name of the allergen correctly, and in the ability to make changes in lifestyle. Hypothetically, it may be more difficult to adopt lifestyle changes regarding avoidance of metals in the environment than to adopt strategies to avoid perfumes. On the other hand, it may be more difficult to remember the name of a fragrance than to remember the name of a metal. However, regarding fragrances, as suggested by others, it might be beneficial to suggest to patients with perfume allergy that they should just remember the group of substances (perfumes) rather than the specific name of a perfume. Moreover, other studies indicate that the ability to recall an allergen is dependent on the number of years after testing, the severity of the dermatitis, and the impact of dermatitis on quality of life. In this study the participants reported mild or moderate symptoms of dermatitis which might have influenced the ability to recall an allergen.

Obviously, there is a gap between remembering as well as understanding the patch testing and making changes in lifestyle. Patch testing is the standard method of diagnosing contact allergy and is fundamental for the correct diagnosis. Moreover, despite correct diagnosis and information to patients, several other factors influence the outcome and prognosis of the disease. As pointed out by Smith, having knowledge of factors that cause disease and what to do about it does not automatically lead to healthy behaviours. However, to improve the situation further interventions are suggested; basic education for patients is outlined by Scalf et al. Moreover, the ‘five stages of change’ programme, originally developed for quitting smoking, could be implemented in a modified form for patients with allergic CD, and specialist nurses could facilitate this process.

In conclusion, the intervention performed did not significantly affect the participants’ ability to remember their contact allergy, or their ability to make lifestyle changes. Therefore, there is a demand for further research concerning how to achieve better understanding of patch testing among patients with CD. Based on our results, further efforts to gain greater benefit from the information and education given would be to concentrate on informing patients over 60 years with multiple allergies. Moreover, our study indicates that the type of allergy (i.e. metal, preservative or perfume) has an influence on the ability to remember the name of the allergen correctly and the ability to make changes in lifestyle. It is therefore very important to take special care with these groups of individuals and to cautiously educate and inform them about the meaning and implications of their positive patch test results.

Acknowledgments

We thank all the staff of the Department of Dermatology and Venereology, Skåne University Hospital, Lund, Sweden, who helped us to perform the study. Special thanks to Agneta Olofsson, Hanna Blomsgren and Inger Nordgren of the Department of Dermatology and Venereology, Lund, for their excellent work in performing the randomization, questionnaire distribution and administration of the study. We are also grateful to Anna Åkesson BSc, of Clinical Studies Sweden, Forum Süder, Skåne University Hospital, Lund, for statistical analysis.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher’s website:

Table S1 Extract from the questionnaire; question number 2.
Table S2 Comparison of the control and intervention groups concerning the ability to recall the correct name of the allergen.
Table S3 (a) Comparison of participants with positive patch test reactions to few (one or two) allergens and multiple (3 or more) allergens and the ability to recall the name of the allergen correctly. (b) A multiple regression model was used to explain the relationship between the variables and calculate odds ratio.
Table S4 (a) Comparison of participants with one positive patch test reaction to a metal, preservative or perfume, and their ability to remember the name of the allergen correctly. (b) A multiple regression model was used to explain the relationship between the variables and calculate odds ratio.
Table S5 Differences in knowledge of where or in what products the contact allergen occurred. A multiple regression model was used to explain the relationship between the variables and calculate odds ratio, among all participants in the study.
Table S6 A multiple regression model was used to explain the relationship between the variables and calculate odds ratio, among participants with one positive patch test reaction to a metal, preservative/perfume, and the ability to make changes to their lifestyle.

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