

ORIGINAL ARTICLE

Simple, low-cost group-counselling programme vs treatment as usual for patients with newly notified occupational hand eczema—Exploratory analyses of effects on knowledge, behavior and personal resources of the randomized PREVEX clinical trial

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Funding information

This work was supported by The Danish Working Environment Research Fund (Arbejdsmiljøforsknings-fonden) and Augustinus Fonden.; Augustinus Fonden

Background: Sickness absence in hand eczema patients has been associated with stress rather than disease severity, indicating that personal aspects regarding hand eczema should be investigated further.

Objectives: To examine whether patient education vs treatment as usual can influence behavior and knowledge regarding skin protection and care, as well as personal resources, in patients with occupational hand eczema.

Methods: PREVEX is an individually randomized clinical trial investigating the 1-year effects of a simple, low-cost group-counselling programme vs treatment as usual for patients with notified occupational hand eczema. Exploratory outcomes were behavior, knowledge, self-efficacy, and self-evaluated skin care ability.

Results: In total, 1668 patients with notified occupational skin disease were invited to participate, of whom 769 were randomized and 756 were analysed: intervention group ($n = 376$) vs control group ($n = 380$). Behavior was improved and the knowledge score increased in the intervention group as compared with the control group (respectively: estimate 0.08; 95%CI: 0.02-0.19; $P = .01$; and estimate 0.49; 95%CI: 0.28-0.70; $P < .001$). Self-efficacy was decreased in the intervention group as compared with the control group (estimate -0.78; 95%CI: -1.25 to -0.30; $P = .001$). No difference was found regarding skin care abilities.

Conclusions: The intervention had a positive influence on 1-year behavior and knowledge, but was insufficient to result in long-term positive changes in personal resources regarding dealing with hand eczema.

KEYWORDS

epidemiology, hand eczema, occupational, patient education, secondary intervention

1 | INTRODUCTION

Occupational hand eczema is a common disease¹ with widespread consequences for the individual patient and society.²⁻⁴ Extensive measures have been taken to reduce the prevalence of occupational

hand eczema,⁵⁻⁷ but with limited success.⁸ This emphasizes the need to investigate new methods for handling this patient group. A possible approach to lessen the burden of occupational hand eczema is the use of educational programmes to increase patients' knowledge about skin care, and to positively influence behavior regarding skin

care. The ultimate goal is to improve health-related quality of life for the individual patient and reduce the disease burden on society by reducing sickness absence and disease-related costs.

Several studies have indicated that patients with occupational or non-occupational hand eczema may know too little about skin care and treatment.^{9,10} Educational programmes for hand eczema patients with a focus on skin care and protection have been successful, and have led to significant improvements in selected groups, as documented in randomized clinical trials from Denmark and The Netherlands.⁵⁻⁷ The interventions in these trials have varied in intensity from 30 minutes of individual counselling to several educational sessions. In Germany, occupational hand eczema patients are offered extensive secondary individual prevention with multidisciplinary (medical and health educational) skin protection seminars and individual counselling on personal skin protection measures together with technical/organizational measures, ensuring that both personal aspects and skin care are taken into consideration.¹¹ The most intensive course offered is a tertiary intervention programme comprising 3 weeks of inpatient care, including education and psychological counselling, as well as dermatological/allergy assessment and treatment for the individual patient.^{11,12} Follow-up results 3 years after tertiary intervention programmes have suggested improvements in prognosis with regard to disease severity, work ability, and health-related quality of life.¹³ However, there was no control group.¹³

Relieving the burden of occupational hand eczema largely corresponds to improvement of the disease. Because of the chronic nature of the hand eczema,¹⁴ health-related quality of life for the individual patient, and the ability to handle the disease, are also important. In a retrospective cross-sectional exploratory study from Germany, occupational hand eczema-related sickness absence was reported to be associated with stress, but not with disease severity.¹⁵ An observational European multicentre cross-sectional study found a stronger association between hand eczema and both depression and anxiety than in healthy controls.¹⁶ It has been suggested that the general ability of patients to self-manage is an important factor for successfully self-managing the disease.¹⁷

The intention of the randomized PREVEX ("PREvention of EXzema") trial was to examine the effectiveness of a simple, low-cost group-counselling programme directed at patients with notified occupational hand eczema vs treatment as usual. We found no effect of the programme on the primary and secondary outcomes, comprising sickness absence, eczema severity, and health-related quality of life.¹⁸ Here, we report the intervention effects on the secondary outcome behaviors of knowledge, self-efficacy, and self-evaluated skin care ability, as well as outcomes defined post hoc, regarding self-evaluated health, self-estimated work-ability, self-evaluated stress and self-evaluated knowledge in the above patients.¹⁹ Self-efficacy is the confidence in one's ability to achieve intended results and the power to affect situations. Self-efficacy is considered to be a predictor for the level of benefit that can be obtained from behavioral modification interventions.²⁰ Apart from behavior, the aforementioned outcomes have not constituted the main interest in previous hand eczema intervention trials.

2 | METHODS

PREVEX is an individually randomized, parallel-group superiority trial. The trial investigated the effects of a short low-cost educational intervention on skin protective behavior and treatment as usual vs only treatment as usual. The trial design has been described in detail in the study protocol.¹⁹ Patients from region Zealand and the capital region of Denmark with an occupational skin disease notified to the Danish Labour Market Insurance during the period July 2012 to November 2013 were eligible for the trial. A self-administered baseline questionnaire was sent by mail to individuals aged 18 to 65 years. Citizens residing in the island of Bornholm and those without a permanent residence in Denmark were excluded.

Inclusion criteria comprised the following data obtained from the baseline questionnaire: self-reported hand eczema, adequately filled-in information about hand eczema severity and occupation, and signed informed consent. Exclusion criteria were age <18 or >65 years, permanent exclusion from the workforce, inability to understand the Danish language, and any serious medical condition that could interfere with the results. A follow-up questionnaire was mailed to the participants 12 months later, addressing the same questions as the first questionnaire.

2.1 | Randomization, blinding, and intervention

Randomization is described in detail elsewhere.¹⁹ Eligible patients were randomized individually 1:1 to either the intervention group or the control group by use of a computer program. The randomization was stratified by age, self-reported hand eczema severity, and profession.¹⁹ It was not possible to blind participants or investigators with respect to treatment, owing to the nature of the design, but data entry was blinded when possible.

The intervention was an educational course on skin protective behavior, given by a doctor and/or nurse, as well as written information about skin care directed at the participant's occupation. The course lasted for 2 hours, and 1 to 14 participants attended. The curriculum of the course was based on an updated version of the previously published 10 recommendations with regard to skin protective behavior.²¹ To ensure a standardized course, a written manual describing the content and structure of the course was followed. Senior doctors trained the 2 teachers who conducted all training before the start of the intervention. Traditional lectures gave information on basic knowledge about the skin, the development of eczema, and recommendations for skin protection and care. Workshops were on hand washing, the use of disinfectants, the use of moisturizers, and the use of different types of gloves. Counselling with job-specific recommendations for skin care and social guidance including information on rules and rights regarding occupational injury were also included in the course. Following the course, a telephone hotline was available for the intervention group.¹⁹ The trial has been approved by the Danish Data Protection Agency (journal number BBH-2011-2033), and has been registered on www.clinicaltrials.gov (identifier: NCT01899287).

2.2 | Questionnaire: Baseline and follow-up

The baseline and the 1-year follow-up questionnaires comprised identical questions on self-assessed hand eczema severity, health-related quality of life, knowledge about skin protection, skin protective behavior, and different aspects of personal resources, the last 3 being, the outcomes considered here.¹⁸

The outcome self-efficacy was validated,²² and all other outcomes, except for 2, had previously been used in other studies. The 2 remaining outcomes were self-constructed questions. Behavior regarding skin protection and skin care was assessed from a total of 9 questions with between 2 and 5 response options, addressing hand washing, the use of protective gloves, the use of hand disinfection, and the use of emollients at work and during leisure time. The responses were scored as 1 to 3, 1 to 4, and 1 to 5, respectively with the least desirable behavior category being scored as 1. Two of the questions (3 and 4 in Table S1) were only relevant for occupations in which protective gloves and emollients were offered at the workplace. Therefore, in order to not exclude the rest of the occupations, the total score (range 7-39) was divided by the number of questions answered (new range 1-4.43). Behavior questions were adapted from the Hand Eczema Trial questionnaire (Table S1).⁵ A total of 9 multiple choice questions, among which only 1 possibility was correct, were used to assess knowledge about skin protection and skin care. A score of 1 was given for each correct answer, and a score of 0 for each incorrect answer (range of scores 0-9) (Table S2). This was adapted from questions previously used in a study with similar participants.¹⁰ Self-efficacy was assessed with a modified edition of the General Self-Efficacy Scale,²³ with slightly different phrasing of questions and answers, but similar content (Table S3), whereby the participants rated each of the 10 questions with either always, usually, rarely, or never, and scores were assigned relative to the answers given (scoring 4 for always, 3 for usually, 2 for seldom, and 1 for never) (range of scores 10-40) (high values being better). Self-evaluated skin care ability was assessed from the answer of almost

always, often, sometimes or rarely to the self-constructed question "do you think you are good enough at taking care of your skin?", and a score between 1 and 4 was awarded (a score of 1 being the best).

Some outcomes were decided after analysis of our data had begun, that is, defined post hoc. Self-estimated health was assessed from the answer of excellent, very good, good, not too good or bad to the question "how do you think your health is all in all?", and a score between 1 and 5 was awarded (a score of 1 being the best), as previously used in a study among the working-age population.²⁴ Self-estimated work ability was evaluated with the question "how do you assess your work ability?", with 4 statements as possible answers: "I manage work without any problems", "I manage work with difficulty", "I can only manage work where special consideration is taken with regard to my health (eg, through reduced hours, new arrangement of the workplace, changed job function)", or "under no circumstances can I manage work", and a score between 1 and 4 was assigned (a score of 1 being the best). The question was part of the work ability index.²⁵⁻²⁷ Self-evaluated frequency of stress was measured with the crude question "how often do you feel stressed?"; the patient could answer "a few times a year", "approximately once a month", "weekly", "a few times a week", or "most days", and a score between 1 and 5 was assigned (a score of 1 being the best). This was adapted from the Copenhagen City Heart Study.²⁸ Self-evaluated knowledge of skin care was evaluated by the answer "yes", "no" or "don't know" to the self-constructed question "do you think you know enough about how to take care of your skin?" It was decided that, for statistical analyses, strata should not comprise <2% of participants. Accordingly, skin care ability and self-evaluated ability to work was reduced from 4 to 3 categories by merging the 2 "worst" categories.

2.3 | Statistics

The sample size estimation was calculated on the basis of the 3 primary outcomes, yielding 742 participants.¹⁹ The exploratory results

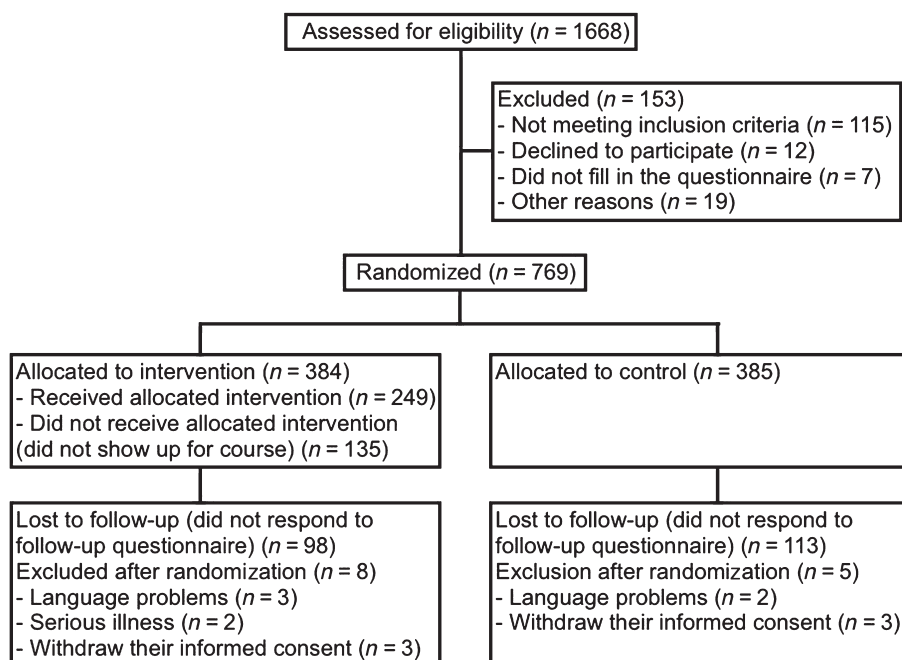


FIGURE 1 Participant flow

of the main analysis were obtained by using adjustment for the protocol-specified stratification variables,¹² namely, baseline severity of hand eczema, age group, and occupational group, as well as the baseline value of the outcome, if available. All main analyses were also performed without adjustment for the protocol-specified stratification variables. The general univariate linear model was used to assess the continuous outcomes.¹⁹ Self-estimated skin care ability was analysed with the proportional odds model.¹⁹ Holm's procedure was performed to adjust for multiple testing.²⁹ As 127 of 376 participants never attended the course in the intervention group, we performed a per-protocol analysis (including only participants who attended the course).

As newer studies have shown a link between factors such as stress and burnout and increased sickness absence in occupational hand eczema patients,¹⁵ we included self-evaluated health, self-evaluated ability to work, stress, and sufficient knowledge about skin care, and examined whether the educational intervention had any effect on the reporting of these characteristics. Examination of baseline data in the trial indicated that healthcare workers differed from other occupations by reporting less severe eczema and lower Dermatology Life Quality Index (DLQI) scores. This motivated us to perform subgroup analyses of healthcare workers and other occupations separately for the 3 primary outcomes. A trend was found, that the effect of the intervention on severity differed between occupations.¹⁸ We wanted to examine whether this could be found among the exploratory outcomes in the present study, by adding a multiplicative interaction term between the subgroup indicator and the intervention indicator. For statistical analysis, *sas* (version 9.4; SAS Institute, Cary, North Carolina) was used.

3 | RESULTS

A total of 1668 individuals with notified occupational skin disease were invited to participate, and 922 (55.3%) responded to the first questionnaire. A total of 769 individuals fulfilled the inclusion criteria and were randomized. Of these, 13 were excluded after randomization (5 controls and 8 from the intervention group) (Figure 1). Therefore, 756 individuals participated in the trial, of whom 376 were in the intervention group and 380 were in the control group (Figure 1). Baseline characteristics are shown in Table 1. On average, the hotline had <1 call per week. Of the 756 participants, 545 (72.1%) returned the 1-year follow-up questionnaire. Of the non-responders, 98 were from the intervention group and 113 were from the control group.

Missing values comprise information that was missing because the patient did not return the follow-up questionnaire, or because some values were missing in a returned questionnaire. The proportion of missing values in the exploratory outcomes and in the post hoc outcomes did not differ significantly ($P > .05$) between the two groups (Table 2).

The exploratory outcome behavior score regarding skin protection and skin care at follow-up was higher in the intervention group than in the control group, and this difference was statistically significant (difference of 0.08; 95%CI: 0.02-0.19; $P = .01$) (Table 3). With a 0.08 mean difference and an overall mean of 2.54, the difference in

TABLE 1 Characteristics of PREVEX trial participants at baseline

	Intervention (n = 376)	Control (n = 380)
Female, n (%)	274 (72.9)	260 (68.4)
Age (years), mean (SD)	39.0 (12.8)	38.5 (12.6)
DLQI, median (Q1-Q3) (n = 755 ^a)	5 (2-10)	5 (2-9)
Social class/status (n = 749), n (%)		
Elementary school	53 (14.3)	69 (18.2)
Vocational education (i.a. apprentices)	145 (39.2)	135 (35.6)
Higher education (1 y to 4.5 y)	110 (29.7)	107 (28.2)
Higher education (<5 y)	62 (16.8)	68 (17.9)
Children under the age of 4 y (n = 755 ^a), n (%)		
Yes	75 (20.0)	57 (15.0)
Own a dishwasher (n = 753), n (%)		
Yes	251 (67.1)	264 (69.7)
Behavior score, mean (SD) (n = 752) (range: 1 [worst] to 4.43 [best])	2.39 (0.36)	2.32 (0.36)
Knowledge score, mean (SD) (n = 755 ^a) (range: 0 [worst] to 9 [best])	7.00 (1.58)	7.06 (1.58)
Self-efficacy score, mean (SD) (n = 714) (range: 10 [worst] to 40 [best])	31.28 (3.42)	31.45 (3.63)
Skincare ability (n = 750), n (%)		
Almost always	133 (35.7)	96 (25.5)
Often	174 (46.6)	189 (50.1)
Sometimes/seldom	66 (17.7)	92 (24.4)
Self-evaluated health (n = 751), n (%)		
Excellent	52 (13.9)	62 (16.4)
Very good	134 (35.9)	148 (39.2)
Good	140 (37.5)	125 (33.1)
Not too good	39 (10.5)	38 (10.1)
Poor	8 (2.1)	5 (1.3)
Self-evaluated ability to work (n = 742), n (%)		
I manage work without any problems	217 (59.0)	237 (63.4)
I manage work with difficulty	97 (26.4)	86 (23.0)
I can only manage work when special consideration is given/ under no circumstances can I manage work	54 (14.7)	51 (13.6)
How often do you feel stressed? (n = 742), n (%)		
A few times a year	112 (30.4)	111 (29.7)
Approximately once a month	103 (28.0)	94 (25.1)
Weekly	84 (22.8)	80 (21.4)
A few times a week	48 (13.0)	63 (16.8)
Most days	21 (5.7)	26 (7.0)
Sufficient knowledge about skincare (n = 634), n (%)		
No	91 (28.8)	83 (26.1)
Yes	225 (71.2)	235 (73.9)

DLQI, Dermatology Life Quality Index; Q1, 25th percentile; Q3, 75th percentile; SD, standard deviation; y, year.

^a One baseline questionnaire was lost after randomization, but before data entry.

change between the 2 groups was 3.1% ($0.08/2.54 \times 100$). The exploratory outcome knowledge score at follow-up was higher in the intervention group than in the control group, and this difference was statistically significant (mean difference score of 0.49; 95%CI: 0.28-0.70; $P < .001$) (Table 3). With a 0.49 mean difference and an overall mean of 7.49, the difference in change between the 2 groups was 6.5% ($0.49/7.49 \times 100$). The significant improvement in knowledge related to the following 4 questions: the importance of not wearing finger rings; a low water temperature when washing hands; the use of hand disinfection instead of hand washing whenever relevant; and the use of cotton gloves underneath protective gloves.

With respect to the exploratory outcome self-efficacy, the score was lower in the intervention group than in the control group, and this difference was statistically significant (mean difference score of -0.78; 95%CI: -1.25 to -0.30; $P = .001$) (Table 3). With a 0.78 mean difference and an overall mean of 31.74, the difference in change between the 2 groups was 2.5% ($0.78/31.74 \times 100$). There was no significant difference in the exploratory outcome skin care ability between the intervention and control groups. The ordinal odds of being in a worse category of skin care ability were 16% higher in the intervention group than in the control group (95%CI: -17% to 63%; $P = .39$) (Table 3). Application of a Holm alpha adjustment procedure did not change the results markedly (knowledge $P < .001$ and self-efficacy $P = .003$).

Regarding post-hoc outcomes self-evaluated health, self-evaluated ability to work, and stress, we found no significant differences between the intervention and control groups (Table 4). A significantly larger proportion of participants in the intervention group answered "yes" to having a sufficient knowledge of skin care (odds ratio 0.44; 95%CI: 0.12-0.95; $P = .04$) (Table 4). The conclusions of the per-protocol analysis were the same as those of the intention-to-treat analysis (Tables 3 and 4).

In a subanalysis comparing healthcare workers with all other occupations, with respect to baseline levels for behavior score, healthcare workers obtained a score of 2.49, whereas all other occupations obtained a score of 2.41. With regard to follow-up behavior, when an interaction term between healthcare workers and all other occupations was added, an insignificant difference between the intervention group and the control group was found in healthcare workers

(estimate -0.02; 95%CI: -0.13 to 0.09; $P = .72$), whereas, in all other occupations, we saw a significant difference in behavior score between the intervention group and the control group (estimate 0.12; 95%CI: 0.05-0.19; $P = .001$). With regard to baseline levels for knowledge score, healthcare workers obtained a score of 7.45 and all other occupations obtained a score of 6.88. Concerning follow-up knowledge, an insignificant difference between the intervention group and the control group was found in the healthcare workers (estimate 0.27; 95%CI: -0.13 to 0.66; $P = .18$), whereas, in other occupations, we saw a significant increase in knowledge score between the intervention group and the control group (estimate 0.58; 95%CI: 0.33-0.83; $P < .0001$). No difference was found in self-efficacy or skincare ability (results not shown).

4 | DISCUSSION

Major findings in these exploratory analyses of a randomized clinical trial include the following: a 2-hour educational programme for newly notified individuals with occupational hand eczema increased knowledge of skin protection and care and beneficial behavior with respect to skin protection and care in the intervention group, whereas self-efficacy decreased as compared with the control group. No difference was found with regard to ability to self-care.

With respect to knowledge, the significant difference of 6.5% indicates that participants in the intervention group had picked up facts from the educational programme that they were able to remember after 1 year. As compared with a previous study measuring knowledge in notified hand eczema patients with similar knowledge questions, the participants in the PREVEX trial had an increased level of knowledge at baseline (78.2% correct answers as compared with 70.4% in previous study).¹⁰ The relatively low percentage increase in knowledge as compared with the control group could be attributable to the already high knowledge level and a ceiling effect. The small but significant improvement regarding beneficial behavior in the intervention group did not significantly influence the primary outcome severity, DLQI, and sickness absence reported elsewhere,⁵ and we conclude that a larger degree of change in behavior is required to achieve a clinical effect.

In a previous randomized clinical trial evaluating an educational intervention in healthcare workers, no significant difference between the intervention and control groups with respect to knowledge was found, but there was a significant improvement in behavior regarding skin protection and care,⁵ indicating that the relationship between knowledge, behavior and outcomes such as severity is not always simple and straightforward. Regarding the statistically significant lower score of 0.78 in outcome self-efficacy in the intervention group, to the best of our knowledge, no minimal clinically important difference is known with respect to this outcome. In a review comparing 13 different studies that measured pain self-efficacy, it was concluded that none of these established a minimal clinically important difference.³⁰ Given a scale from 10 to 40, we assume that this difference is too small to be clinically relevant.

However, when an overall health behavior model such as the Health Action Process Approach (HAPA) model is applied to the results, the interpretation of self-efficacy could be interpreted

TABLE 2 Missing data from PREVEX trial participants at follow-up for the explorative outcomes behavior, knowledge, self-efficacy and skin care ability and post hoc outcomes health, ability to work, stress, and self-evaluated sufficient knowledge about skin care

	Intervention (n = 376)	Control (n = 380)	P value
Behavior, n (%)	98 (26.1)	114 (30.0)	.23
Knowledge score, n (%)	98 (26.1)	113 (29.7)	.26
Self-efficacy, n (%)	115 (30.6)	123 (32.4)	.60
Skin care ability, n (%)	98 (26.1)	115 (30.3)	.20
Self-evaluated health, n (%)	100 (26.6)	115 (30.3)	.26
Self-evaluated ability to work, n (%)	101 (26.9)	119 (31.3)	.18
Stress, n (%)	101 (26.9)	117 (30.8)	.23
Sufficient knowledge about skincare, n (%)	98 (26.1)	115 (30.3)	.20

P values were generated with χ^2 tests.

TABLE 3 Intention-to-treat and per-protocol analyses of crude and adjusted estimates for explorative outcomes in the intervention group as compared with the control group

	Intention-to-treat analysis			Per-protocol analysis					
	Mean (SD)	Crude Mean difference (95%CI)	P value	Adjusted Mean difference (95%CI)	P value	Mean (SD)	Crude Mean difference (95%CI)	Adjusted Mean difference (95%CI)	P value
Behavior									
Intervention (n = 278)	2.56 (0.39)	0.11 (0.04-0.17)	.002	0.08 (0.02-0.19)	.01	2.62 (0.35)	0.13 (0.07-0.20)	0.11 (0.04-0.17)	<.001
Control (n = 266)	2.45 (0.39)	Ref.		Ref.		2.45 (0.39)	Ref.	Ref.	
Knowledge									
Intervention (n = 278)	7.71 (1.41)	0.45 (0.20-0.69)	<.001	0.49 (0.28-0.70)	<.001	7.89 (1.23)	0.67 (0.46-0.89)	0.69 (0.48-0.91)	<.001
Control (n = 267)	7.27 (1.49)	Ref.		Ref.		7.27 (1.49)	Ref.	Ref.	
Self-efficacy									
Intervention (n = 261)	31.36 (3.35)	-0.80 (-1.40 to -0.19)	.01	-0.78 (-1.25 to -0.30)	.001	31.20 (3.34)	-0.95 (-1.61 to -0.30)	-0.72 (-1.23 to -0.20)	.006
Control (n = 257)	32.15 (3.68)	Ref.		Ref.		32.15 (3.68)	Ref.	Ref.	
Skincare ability									
Intervention	n (%)	OR (95%CI)	P value	OR (95%CI)	P value		OR (95%CI)	OR (95%CI)	P value
Almost always	105 (37.8)	0.96 (0.71-1.33)	.85	1.16 (0.83-1.63)	.39	75 (36.2)	1.01 (0.72-1.43)	1.23 (0.85-1.77)	.27
Often	138 (49.6)					106 (51.2)			
Sometimes/seldom	35 (12.6)					26 (12.6)			
Control		Ref.		Ref.			Ref.	Ref.	
Almost always	105 (39.6)					105 (39.6)			
Often	116 (43.8)					116 (43.8)			
Sometimes/seldom	44 (16.6)					44 (16.6)			

CI, confidence interval; OR, odds ratio; Ref., reference; SD, standard deviation.

TABLE 4 Intention-to-treat and per-protocol analyses of crude and adjusted odds ratios (ORs) for post hoc outcomes in the intervention group as compared with the control group

	Intention-to-treat analysis					Per-protocol analysis				
	<i>n</i> (%)	Crude OR (95%CI)	<i>P</i> value	Adjusted OR (95%CI)	<i>P</i> value	<i>n</i> (%)	Crude OR (95%CI)	<i>P</i> value	Adjusted OR (95%CI)	<i>P</i> value
Self-evaluated health (missing: 216 and 159)										
Intervention		1.22 (0.90-1.66)	.21	1.15 (0.83-1.60)	.39		1.35 (0.97-1.89)	.08	1.24 (0.87-1.77)	.24
Excellent	39 (14.2)					25 (12.2)				
Very good	104 (37.8)					75 (36.6)				
Good	98 (35.6)					82 (40.0)				
Less good	27 (9.8)					17 (8.3)				
Bad	7 (2.5)					6 (2.9)				
Control		Ref.		Ref.			Ref.		Ref.	
Excellent	44 (16.6)					44 (16.6)				
Very good	112 (42.3)					112 (42.3)				
Good	75 (28.3)					75 (28.3)				
Less good	24 (9.1)					24 (9.1)				
Bad	10 (3.8)					10 (3.8)				
Self-evaluated ability to work (missing: 220 and 163)										
Intervention (<i>n</i> = 275)		1.12 (0.79-1.60)	.51	1.12 (0.75-1.66)	.57		1.15 (0.79-1.67)	.48	1.06 (0.69-1.64)	.78
No problems	180 (65.5)					133 (64.9)				
Difficulties	53 (19.3)					41 (20.0)				
Only if considerations are given/not capable of work	42 (15.3)					31 (15.1)				
Control (<i>n</i> = 261)		Ref.		Ref.			Ref.		Ref.	
No problems	176 (67.4)					176 (67.4)				
Difficulties	53 (20.3)					53 (20.3)				
Only if considerations are given/not capable of work	32 (12.3)					32 (12.3)				
Stress (missing: 218 and 163)										
Intervention		1.12 (0.82-1.51)	.48	1.22 (0.89-1.67)	.23		1.29 (0.93-1.78)	.13	1.32 (0.94-1.87)	.11
A few times a year	75 (27.4)					47 (23.0)				
Approximately once a month	86 (31.4)					66 (32.4)				
Weekly	54 (19.7)					46 (22.5)				
A few times a week	38 (13.9)					28 (13.7)				
Most days	21 (7.7)					17 (8.3)				
Control		Ref.		Ref.			Ref.		Ref.	
A few times a year	85 (32.4)					85 (32.4)				
Approximately once a month	66 (25.2)					66 (25.2)				
Weekly	60 (22.9)					60 (22.9)				
A few times a week	35 (13.4)					35 (13.4)				
Most days	16 (6.1)					16 (6.1)				
Sufficient knowledge about skin care (missing: 208 and 192)										
Intervention		0.55 (0.27-1.13)	.10	0.44 (0.12-0.95)	.04		0.42 (0.18-0.98)	.046	0.34 (0.14-0.83)	.02
No	12 (5.4)					8 (4.1)				
Yes	212 (94.6)					189 (95.9)				
Control		Ref.		Ref.			Ref.		Ref.	
No	21 (10.1)					21 (10.1)				
Yes	186 (89.9)					186 (89.9)				

CI, confidence interval; Ref., reference.

somewhat differently.³¹ Knowledge could be translated into the concept risk perception in the HAPA model. The increase in knowledge could initially have increased the action and maintenance of self-efficacy but could unintentionally have caused a lower recovery of self-efficacy in the intervention group, owing to increased knowledge of the chronic nature of hand eczema.

With regard to skin care ability, this question was, in contrast to the other exploratory outcomes, a non-validated question that had not previously been used in other studies, so a certain amount of caution is needed when deciding whether the intervention had an effect on the participants' ability to care for their skin. On the other hand, as none of the other outcomes measuring different aspects of personal resources had a significant beneficial effect, this result seems to be in line with the other findings.

Regarding our post hoc outcomes self-evaluated health, self-evaluated ability to work, and stress, the intervention did not markedly influence these outcomes. A likely explanation is that the educational intervention was too short to have a lasting impression on personal resources. With respect to self-assessed knowledge, this had a higher score in the intervention group, in line with the higher knowledge score as assessed from knowledge questions in this group. Concerning the analysis comparing healthcare workers and other occupations, the results regarding behavior and knowledge both showed that healthcare workers did not improve significantly with respect to behavior or knowledge, so the difference found in the main analysis was mainly attributable to the improvements in behavior and knowledge in all other occupations. This could be partly attributable to the fact that healthcare workers already knew more at baseline, and therefore did not learn as much. Another possible explanation, as indicated in the previous interaction analyses on the primary outcomes severity and sickness absence, is that the intervention could have had a different and negative effect on healthcare workers as compared with other occupations.¹⁸

Considering previous results showing that not only severity influences prognosis (assessed as sickness absence and health-related quality of life) but that factors such as personal resources (stress and burnout) are also important,¹⁵ it is interesting that this education intervention had no effect on these outcomes (self-evaluated work ability, stress, and self-evaluated health). It is evident that not only knowledge is necessary for hand eczema patients to master their disease. A longer-lasting or repeated course also addressing personal resources could possibly have positively influenced the results. The intervention in PREVEX was 2 hours long and group-based. It is possible that an individual intervention would be more effective. The rationale for having a 2-hour group-based intervention was to examine whether a sufficient effect could be obtained with a low-cost intervention that is easy to implement. Another factor is the timing of the evaluation after 1 year—a shorter follow-up period might have shown an effect of the intervention, which may have diminished over the course of 1 year. However, a theory regarding changes in health behavior states that certain stages of change exist, with defined time intervals linked to each, and that a person is in an action stage for 6 months before a maintenance stage or relapse takes place.³² Thus, evaluation after only 6 months would fall into the action stage, and could give a potentially overoptimistic estimate of the long-term

effect of the intervention. Another explanation for the lack of effect in our trial is that a different kind of intervention from the offered course and hotline is needed to have an impact on personal resources, as 35% of individuals never showed up for the course, and the hotline was used very little.

Strengths of the PREVEX trial include its randomized nature and the fact that it comprised patients with newly notified occupational hand eczema, a population that has not previously been addressed by intervention studies. The trial was designed to minimize the risk of both systematic error and random error, and resulted in homogeneous groups (Table 1).¹⁹ Shortcomings include a response for the baseline questionnaire of only 55%. It is not known whether these potential participants could have changed the results. With respect to the knowledge score, it was, in theory, possible to "cheat", as the questionnaire was sent to the participants' homes, and they could search for knowledge elsewhere to obtain the correct answers.

5 | CONCLUSION

The intervention, designed as a 2-hour, low-cost educational programme, positively influenced knowledge and behavior regarding skin protection and care when evaluated after 1 year. However, the intervention had a small negative effect with respect to self-efficacy, and other parameters such as ability to self-care and personal resources were not influenced. We conclude that the intervention was insufficient to have a long-term impact on personal resources regarding the handling of occupational hand eczema. In future research, the impact of longer and more profound courses, possibly with individual counselling and with participants stratified for occupation, should be examined.

ACKNOWLEDGEMENTS

Esben Flachs is acknowledged for statistical support.

CONFLICTS OF INTEREST

The authors declare no potential conflict of interests.

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REFERENCES

1. Thyssen JP, Johansen JD, Linneberg A, Menné T. The epidemiology of hand eczema in the general population—prevalence and main findings. *Contact Dermatitis*. 2010;62:75-87.
2. Lerbaek A, Kyvik KO, Ravn H, Menné T, Agner T. Clinical characteristics and consequences of hand eczema—an 8-year follow-up study of a population-based twin cohort. *Contact Dermatitis*. 2008;58: 210-216.
3. Meding B, Swanbeck G. Consequences of having eczema. *Contact Dermatitis*. 1990;23:6-14.

4. Meding B, Wrangsjö K, Järvholm B. Fifteen-year follow-up of hand eczema: persistence and consequences. *Br J Dermatol*. 2005;152: 975-980.
5. Ibler KS, Jemec GB, Diepgen TL, et al. Skin care education and individual counselling versus treatment as usual in healthcare workers with hand eczema: randomised clinical trial. *BMJ*. 2012;345:e7822.
6. van Gils RF, Boot CRL, Knol DL, et al. The effectiveness of integrated care for patients with hand eczema: results of a randomized, controlled trial. *Contact Dermatitis*. 2012;66:197-204.
7. Møllerup A, Veien NK, Johansen JD. Effectiveness of the healthy skin clinic—a randomized clinical trial of nurse-led patient counselling in hand eczema. *Contact Dermatitis*. 2014;71:202-214.
8. Labour Market Insurance (Arbejdsmarkedets Erhvervssikring), TABLE 3. Available at: <https://aes.dk/da/Statistik/Arbejdsskader/Erhvervssygdomme-fordelt-pAa-diagnoser/2015.aspx>. Accessed October 1, 2017.
9. Møllerup A, Johansen JD, Thing LF. Knowledge, attitudes and behaviour in everyday life with chronic hand eczema: a qualitative study. *Br J Dermatol*. 2013;169:1056-1065.
10. Fisker MH, Ebbelhøj NE, Jungersted JM, Agner T. What do patients with occupational hand eczema know about skin care? *Contact Dermatitis*. 2013;69:93-98.
11. Skudlik C, Weisshaar E, Scheidt R, et al. Multicenter study "medical-occupational rehabilitation procedure skin—optimizing and quality assurance of inpatient-management (ROQ)". *J Dtsch Dermatologischen Gesellschaft*. 2009;7:122-126.
12. Weisshaar E, Skudlik C, Scheidt R, et al. Multicentre study "rehabilitation of occupational skin diseases—optimization and quality assurance of inpatient management (ROQ)"—results from 12-month follow-up. *Contact Dermatitis*. 2013;68:169-174.
13. Brans R, Skudlik C, Weisshaar E, et al. Multicentre cohort study "rehabilitation of occupational skin diseases—optimization and quality Assurance of Inpatient Management (ROQ)": results from a 3-year follow-up. *Contact Dermatitis*. 2016;75:205-212.
14. Meding B, Lantto R, Lindahl G, Wrangsjö K, Bengtsson B. Occupational skin disease in Sweden—a 12-year follow-up. *Contact Dermatitis*. 2005;53:308-313.
15. Böhm D, Stock Gissendanner S, Finkeldey F, et al. Severe occupational hand eczema, job stress and cumulative sickness absence. *Occup Med (Lond)*. 2014;64:509-515.
16. Dalgard FJ, Gieler U, Tomas-Aragones L, et al. The psychological burden of skin diseases: a cross-sectional multicenter study among dermatological out-patients in 13 European countries. *J Invest Dermatol*. 2015;135:984-991.
17. Holm S. Justifying patient self-management—evidence based medicine or the primacy of the first person perspective. *Med Health Care Philos*. 2005;8:159-164.
18. Fisker MH, Ebbelhøj NE, Vejstrup SG, et al. Prevention of hand eczema: effect of a skin educational programme versus treatment as usual in workers with notified occupational hand eczema. The randomised clinical PREVEX trial. *Scand J Occup Environ Med*. 2018;44: 212-218.
19. Fisker MH, Agner T, Lindschou J, et al. Protocol for a randomised trial on the effect of group education on skin-protective behaviour versus treatment as usual among individuals with newly notified occupational hand eczema—the prevention of hand eczema (PREVEX) trial. *BMC Dermatol*. 2013;19:13-16.
20. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev*. 1977;84:191-215.
21. Agner T, Held E. Skin protection programmes. *Contact Dermatitis*. 2002;47:253-256.
22. Sherer M, Maddux EJ. The self-efficacy scale—construction and validation. *Psychol Rep*. 1982;51:663-671.
23. The General Self-Efficacy Scale (GSE). Available at: <https://userpage.fu-berlin.de/health/engscal.htm>. Accessed October 1, 2017.
24. Miilunpalo S, Vuori I, Oja P, Pasanen M, Urponen H. Self-rated health status as a health measure: the predictive value of self-reported health status on the use of physician services and on mortality in the working-age population. *J Clin Epidemiol*. 1997;50:517-528.
25. Tuomi K, Ilmarinen J, Jahkola A, Katajarinnel TA. *Work Ability Index*. Occupational Health Care; 1998.
26. Tuomi K, Toikkanen J, Eskelinen L, et al. Mortality, disability and changes in occupation among aging municipal employees. *Scand J Work Environ Health*. 1991;17:58-66.
27. Ilmarinen J. Work ability—a comprehensive concept occupational for health research and prevention. *Scand J Work Environ Health*. 2009; 35:1-5.
28. Nielsen NR, Kristensen TS, Schnohr P, Grønbaek M. Perceived stress and cause-specific mortality among men and women: results from a prospective cohort study. *Am J Epidemiol*. 2008;168:481-491.
29. Holm SA. Simple sequentially rejective multiple test procedure. *Scand J Stat*. 1979;6:65-70.
30. Miles CL, Pincus T, Carnes D, Taylor SJC, Underwood M. Measuring pain self-efficacy. *Clin J Pain*. 2011;27:461-470.
31. Schwarzer R. Modeling health behavior change: how to predict and modify the adoption and maintenance of health behaviors. *Appl Psychol*. 2008;57:1-29.
32. Prochaska JO, Velicer WF. The transtheoretical change model of health behavior. *Am J Health Promot*. 1997;12:38-48.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Fisker MH, Agner T, Sørensen JA, et al. Simple, low-cost group-counselling programme vs treatment as usual for patients with newly notified occupational hand eczema—Exploratory analyses of effects on knowledge, behavior and personal resources of the randomized PREVEX clinical trial. *Contact Dermatitis*. 2018;1-9. <https://doi.org/10.1111/cod.13003>