

Multicentre cohort study ‘Rehabilitation of Occupational Skin Diseases – Optimization and Quality Assurance of Inpatient Management (ROQ)’: results from a 3-year follow-up

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Summary

Background. A tertiary individual prevention programme (TIP) is offered to patients with severe occupational skin disease (OSD) in Germany. Previously, it was shown that the burden of OSDs is considerably reduced in patients up to 1 year after the TIP.

Objectives. To evaluate the long-term effects of the TIP.

Patients and methods. In a prospective multicentre cohort study, the clinical and patient-reported outcome data 3 years after the TIP were evaluated.

Results. Of the 1788 patients initially included in the study, 1410 were available for the 3-year follow-up analysis. The severity of OSD, the use of topical corticosteroids and days of absence from work were significantly reduced 3 years after the TIP, and the quality of life and skin protective behaviour were significantly improved. Of the patients, 96.9% were able to resume work. One thousand one hundred and sixty-six patients (82.7%) were still working 3 years after the TIP, 874 of them (75.0%) in the same occupational field. Hairdressers had the lowest rate of remaining in their original profession (41.3%).

Conclusions. The follow-up during 3 years of this unique cohort of patients with OSDs shows that the TIP is associated with sustained improvements in terms of disease severity, ability to work, quality of life, and prognosis.

Key words: contact dermatitis; evaluation; follow-up; hand eczema; intervention; occupational skin diseases; prevention.

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Occupational skin diseases (OSDs) are the most common occupational diseases in industrial countries (1, 2). In Germany, they constitute 35% of all notified occupational diseases. They are associated with substantial reductions in quality of life (3, 4), a poor prognosis (5, 6), and a considerable socio-economic burden (7, 8). The estimated annual costs related to OSDs in Germany exceed €1.5 billion. They are mainly related to work absenteeism and lack of productivity, which particularly affect the competitiveness of small and medium-sized enterprises (9).

In Germany, a multi-step intervention approach ranging from primary to secondary and finally tertiary prevention measures has been established to tackle the burden of OSDs (10). This approach is funded by the statutory accident insurance organizations, and offers interventions that depend on the severity and stage of disease. Patients with severe OSD have a particularly high number of days of absence from work, and are at high risk of leaving their occupation, which may lead to costly retraining or compensation, and an uncertain future in the labour market (8). Therefore, as part of the multi-step approach, patients with severe OSD are offered the opportunity to take part in an interdisciplinary integrated prevention programme [tertiary individual prevention programme (TIP)] if secondary prevention measures fail (10, 11). The TIP is based on a 3-week inpatient phase in a specialized centre providing intensified dermatological diagnostics and treatment, as well as health education and psychological counselling, followed by a 3-week outpatient phase under the supervision of a local dermatologist before the patients return to work. Afterwards, the patients receive continuous outpatient dermatological treatment and surveillance. If needed, the TIP centres provide further adjustments of measures.

To evaluate the effectiveness of the TIP, a prospective multicentre cohort study termed 'Rehabilitation of Occupational Skin Diseases – Optimization and Quality Assurance of Inpatient Management (ROQ)' was initiated in 2005 (11). Until 2009, 1788 patients taking part in the TIP were recruited. The follow-up results of these patients until 4 weeks (12) and 1 year (13) after completion of the TIP were published previously. These results show that the TIP reduces the severity of the disease and work absenteeism and improves quality of life. However, the sustainability of these positive effects over longer periods has been uncertain. The long-term prognosis for TIP patients remaining in the workforce is of particular interest. Therefore, 3 years after the intervention, the recruited patients were re-evaluated. Here, we present the results of this long-term follow-up.

Patients and Methods

The TIP and the design of the ROQ study have been described in detail elsewhere (11–13). Briefly, the TIP consists of a 3-week inpatient intervention phase in a specialized centre, including diagnostics, treatment, and patient education, followed by a 3-week outpatient phase with absence from work under the supervision of a local dermatologist in the patient's hometown. After the TIP, patients ideally return to their workplaces with improved skin condition and optimized skin protection measures, and are under continuous outpatient supervision by a dermatologist. The measure is funded by the statutory accident insurance organization in charge, which also ensures that the patient receives the selected personal protective equipment and, if necessary, initiates workplace visits, for example to implement technical preventive measures, or eliminate relevant allergens on the basis of information collected during the TIP.

The ROQ study is a prospective, longitudinal, multicentre cohort study. Of the patients taking part in the TIP, 1788 gave their written informed consent, and were consecutively recruited in the five participating centres throughout Germany between November 2005 and December 2009. Standardization of procedures in all centres was guaranteed by a detailed operation manual, train-the-trainer schooling, and quality circles. Assessments of patients were carried out at admission (T1), at discharge (T2), shortly before return to the workplace (T3), 4 weeks after return to the workplace (T4), and 12 months (T5) and 3 years (T6) later. The 3-year follow-up was concluded in December 2012. At each time point, the severity of the disease was assessed with the Osnabrueck Hand Eczema Severity Index (OHSEI) (14, 15) and another score published in the *Bamberg Medical Bulletin*, which also covers OSDs not limited to the hands (16). In addition, the patients were asked to provide self-assessment of disease severity, and how confident they were that they would be able to remain in their occupations. At the same time, the quality of life was evaluated with both the Dermatology Life Quality Index (DLQI) (17) and the Life Quality Index Occupational Dermatoses (LIOD) (18). Among other variables regarding occupational stress and individual skin protective behaviour, the total number of days of absence from work attributable to OSDs was assessed. Moreover, it was noted whether the participants had resumed work, and whether they were able to continue to work and remain in their professions (including having different work tasks) or occupational fields (including changing profession, but still performing similar work tasks) after the TIP.

All participating centres independently obtained ethical approval from their respective institutions' ethics

committees. The study was performed in full accordance with the World Medical Association's Declaration of Helsinki, and the results are reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations (19).

Statistical analyses were conducted with SPSS™ 20 (IBM SPSS Statistics, Armonk, NY, USA). Differences between baseline and follow-up were calculated with a paired *t*-test for dependent samples for continuous variables, with the Wilcoxon signed-rank test for ordinal variables, and with the McNemar test for dichotomous variables. Differences were considered to be significant if the *p*-value obtained was <0.05.

Results

Follow-up at T6 (3 years)

Loss to follow-up was minimal. Of the 1788 patients who were initially included in the study, 1410 (response rate of 78.9%) took part in the follow-up 3 years after the TIP (T6). The participation rate between the 1- and 3-year follow-ups was 90%. Seventy-nine patients (4.4%) dropped out from the study between T1 and T6, because of death, severe other illness, and withdrawal for 'personal reasons'. Common reasons for the other 299 patients not participating in the T6 follow-up were change of address (*n* = 28) and 'personal reasons' (*n* = 59). Eighty-five patients did not appear at the appointment, without apology, and 127 did not respond to the invitation at all. A sensitivity analysis did not show significant differences in clinical and demographic variables between those for whom 3-year follow-up data were available (*n* = 1410) and those for whom they were not (*n* = 299) (data not shown). Because of the high response rate, no significant differences were found with regard to the sociodemographic data and diagnoses previously published (12, 13). Seven hundred and eight patients (50.2%) were men. The average age was 44.0 ± 11.7 years. The most frequent occupational groups were healthcare (29.5%), metal industry (29.5%), hairdressing (8.6%), building (8.4%), food handling (5.9%), and cleaning (4.8%). Hand eczema (HE) was diagnosed in 1316 patients (93.3%). Of these, 1071 (81.4%) had an irritant HE component, 721 (54.8%) an atopic HE component, and 534 (40.6%) an allergic HE component. Eight hundred and ten (61.6%) patients suffered from an overlap-type HE, that is, with combined aetiologies.

Return to workforce

Within the 3 years after the TIP, 96.9% of the 1410 evaluated patients were able to resume work at some

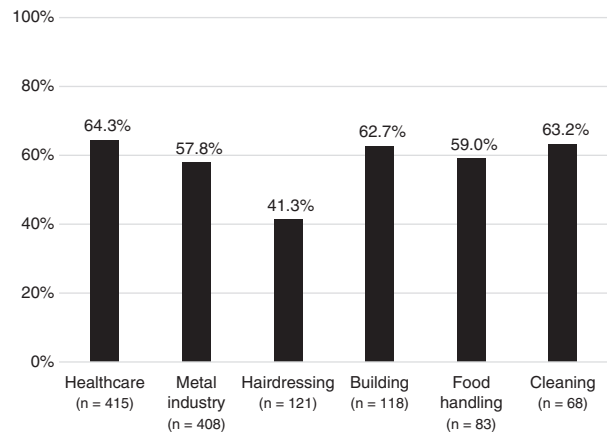


Fig. 1. Three-year follow-up: percentage of patients who reported working in the same occupational field as prior to the intervention, stratified by occupation.

point. At T6, 1166 patients (82.7%) were still working. Of these, 874 (75.0%) were working in the same occupational field as before the TIP. Accordingly, the type and extent of occupational exposures (e.g. amount of wet work) had not changed considerably in comparison with T1 (data not shown). Four hundred and six patients (28.8%) had left the original occupational field, most of them because of the skin disease (75.6%). At T6, 94 patients were unemployed (6.7%), 81 were taking part in a retraining programme (5.7%), and 68 were retired (4.8%). For 1 patient, information was missing. Among the 121 recruited hairdressers for whom follow-up data were available, only 50 (41.3%) were still working in the same occupational field 3 years after the TIP (Fig. 1). Sixty-three hairdressers (52.1%) reported that they had given up the occupation because of the skin disease. Twenty-eight (23.1%) were already working in a different occupation, and 29 (24.0%) were being retrained. Thus, ~50% of the recruited hairdressers had already changed job or were about to do so.

Severity of HE

In those evaluated 3 years after the TIP (*n* = 1410), the severity of HE as assessed from the OHSI score was significantly lower than at admission to the inpatient phase (*p* < 0.001) (Table 1), and even lower than at T5 (*p* < 0.01). Even in the subgroup of those who were working in the same occupational field 3 years after the TIP (*n* = 874) the severity of HE was significantly lower than at admission (*p* < 0.001) (Table 1). Similarly, the severity score used for OSDs not limited to the hands and the patient-based self-assessment of the severity were

significantly lower than at admission (Table 1). Complete healing of occupational skin lesions was found in 445 patients (31.6%). Among those who were working at T6, the healing rate was similar ($n = 324$, 28.2%). Only 56 (4.9%) still had severe skin lesions.

Quality of life

The quality of life as assessed with the DLQI and LIOD 3 years after the TIP was significantly better than at admission ($p < 0.001$), even in the subgroup of those who continued working in the same occupational field after the TIP (Table 1).

Use of topical corticosteroids

In the year prior to the TIP, 89.0% of all patients had applied topical steroids. Of these, 56.1% had used high-potency topical steroids. Three years after the TIP, only 46.7% ($n = 638$) were using topical steroids ($p < 0.001$) (Table 1), including 24.6% who were using high-potency topical steroids. This decrease was similarly significant in the subgroup of those who were still working in the same occupational field as prior to the TIP ($p < 0.001$) (Table 1).

Days of absence from work attributable to OSDs

Of those who were still working in the same occupational field 3 years after the TIP ($n = 874$), 75.7% reported no work absenteeism because of OSDs during the second and third years of follow-up. In contrast, only 410 of them (47.0%) had reported no work absenteeism because of OSDs in the year before the TIP. In those still working in the same occupational field for whom data regarding work absenteeism were available both for T1 and T6 ($n = 836$), the average annual number of days of absence from work dropped significantly, from 23.3 days in the year before the TIP to 7.4 days per year for the second and third years of follow-up ($p < 0.001$) (Table 2).

Other indicators

In those who reported, at follow-up, working in the same occupational field as prior to the TIP, the frequency of hand washing was significantly decreased ($p < 0.001$) but the frequency of hand disinfection was significantly increased ($p < 0.001$) as compared with admission to the TIP (Table 2). In particular, a high frequency of hand washing ($> 10/\text{day}$) was reduced, whereas the frequency of hand disinfection was, overall, increased. The use of skin protection creams and emollients was significantly higher than before ($p = 0.025$ and $p < 0.001$,

respectively). The use of protective gloves was unchanged (Table 2).

One thousand and ninety patients (95.1%) who were still working at T6 appeared to be motivated to continue the use of skin protection measures. Three years after the TIP, a significantly higher number of those still working in the same occupational field judged their OSDs to be less severe ($p = 0.003$) (Table 1), and were more optimistic about remaining in their occupation than at admission ($p < 0.001$) (Table 2). Nine hundred and forty-three patients (78% of 1210) stated that they were able to sufficiently deal with their skin disease. Ninety-eight per cent of 1220 had a positive impression of the seminars, and would recommend them to others.

Discussion

Here, we present the 3-year follow-up results of a large prospective intervention study evaluating the effectiveness of the TIP for patients with severe OSDs. The data confirm the promising results published previously for the 4-week follow-up (12) and the 1-year follow-up (13) periods, and thus emphasize the sustainability of the positive effects of the intervention. The low drop-out rate and the drop-out analysis suggest good reliability and validity of the findings.

Patients with severe OSDs are at risk of leaving their profession and even the workforce (6, 8). Here, we have shown that 97% of the recruited patients, who all suffered from severe OSDs at admission, were able to resume work at some point after taking part in the TIP. At the 3-year follow-up, 82.7% of patients were still in the active workforce. This was a slightly lower rate than observed 1 year after completion of the TIP, when 87.4% of patients were still working (13). However, it needs to be considered that some of the patients had reached full retirement age, and had thus discontinued working in the meantime. Three years after the TIP, only 6.7% of the patients were unemployed, and 5.7% were taking part in retraining. Notably, 75.0% of the patients who were still in the active workforce were working in the same occupational field as prior to the TIP, which underscores the sustained success of the programme in limiting the need for compensation and retraining. This may result in tremendous cost savings, especially as the estimated cost for retraining in Germany is approximately €100 000 per person (7). Moreover, retraining does not guarantee successful re-employment, and may contribute to a lack of a skilled workforce in professions with a risk of OSD.

By far the worst prognosis with regard to remaining in the original occupations was observed in hairdressers.

Table 1. Three-year follow-up: primary outcomes of all patients (A) and of those who reported working in the same occupational field as prior to the intervention (B)

Primary outcomes			Admission (T1)	Three-year follow-up (T6)	N _{total}	p
OHSI ^a	A		6.37 ± 3.46 6 (4–9)	2.81 ± 2.90 2 (1–4)	1410	<0.001 ^b
	B		6.22 ± 3.44 6 (4–8)	3.07 ± 2.95 2 (1–4)	874	<0.001 ^b
Severity of OSD ^c , n (%)	A	1	18 (1.3)	445 (31.6)	1410	<0.001 ^b
		2	427 (30.3)	640 (45.4)		
		3	681 (48.3)	259 (18.4)		
		4	283 (20.1)	66 (4.7)		
	B	1	14 (1.6)	215 (24.6)	874	<0.001 ^b
		2	281 (32.2)	433 (49.5)		
		3	408 (46.7)	180 (20.6)		
		4	171 (19.6)	46 (5.3)		
Self-assessment of OSD severity ^d , n (%)	A	1	50 (3.6)	398 (28.3)	1408	<0.001 ^b
		2	1013 (71.9)	596 (42.3)		
		3	233 (16.5)	296 (21.0)		
		4	97 (6.9)	103 (7.3)		
		5	15 (1.1)	15 (1.1)		
	B	1	33 (3.8)	186 (21.3)	874	0.005 ^b
		2	621 (71.1)	424 (48.5)		
		3	143 (16.4)	177 (20.3)		
		4	64 (7.3)	76 (8.7)		
		5	13 (1.5)	11 (1.3)		
DLQI ^a	A		10.23 ± 6.50 9 (5–15)	5.00 ± 6.17 2 (0–8)	1257	<0.001 ^b
	B		9.62 ± 6.32 9 (4–14)	5.24 ± 6.00 3 (1–8)	779	<0.001 ^b
LIOD ^a	A		17.97 ± 4.66 18 (15–21)	12.11 ± 4.90 11 (8–15)	1253	<0.001 ^b
	B		17.04 ± 4.52 17 (14–20)	12.36 ± 4.51 12 (9–15)	784	<0.001 ^b
Topical corticosteroids within previous 12 months, n (%)	A		1216 (89.0)	638 (46.7)	1367	<0.001 ^e
	B		747 (87.6)	459 (53.8)	853	<0.001 ^e

A, all patients at T6; B, patients who worked in the same occupational field at T6 as prior to the tertiary individual prevention programme; DLQI, Dermatology Life Quality Index; LIOD, Life Quality Index Occupational Dermatoses; OHSI, Osnabrueck Hand Eczema Severity Index; OSD, occupational skin disease.

^aMean ± standard deviation (additionally given for ordinal scores to enable comparison with previous literature), median (interquartile range: Q1–Q3).

^bWilcoxon signed-rank test.

^cAccording to the *Bamberg Medical Bulletin*.

^dAs compared with the worst severity within the last 6 months.

^eMcNemar test.

Three years after the TIP, only 41.3% of the hairdressers available for evaluation were still working in the same occupation. This was in line with previous data showing that hairdressers have the highest risk of leaving the occupation after the TIP as compared with patients working in other professions (10). Hairdressers are exposed extensively to wet work, resulting in an early onset of OSD, often already during apprenticeship (20). Moreover, allergic contact dermatitis caused by allergens from the workplace is a common cause of OSDs in hairdressers

(21). For hairdressers, it is difficult to completely avoid harmful exposures at work, because, often, replacement of the relevant allergens is not possible, and the wearing of protective gloves during all work procedures (e.g. hair cutting) is not yet accepted everywhere. Therefore, despite intensive efforts, preventing skin lesions in hairdressers remains a major challenge. In particular, young hairdressers with OSDs tend to leave the occupation (10, 22), given that retraining and reorientation is worthwhile in relation to their age.

Table 2. Three-year follow-up: selected outcomes of patients who reported working in the same occupational field as prior to the intervention

Selected outcomes	Admission (T1)	Three-year follow-up (T6)	N _{total}	<i>p</i>
Days of absence from work ^{ab}	23.25 ± 48.42	7.40 ± 28.35	836	<0.001 ^c
Hand washing frequency, n (%)			872	<0.001 ^d
Never	6 (0.7)	11 (1.3)		
<10/day	571 (65.5)	669 (76.7)		
10–20/day	231 (26.5)	166 (19.0)		
>20/day	64 (7.3)	26 (3.0)		
Hand disinfection frequency, n (%)			872	<0.01 ^d
Never	571 (65.5)	537 (61.6)		
<10/day	163 (18.7)	179 (20.5)		
10–20/day	79 (9.1)	100 (11.5)		
>20/day	59 (6.8)	56 (6.4)		
Use of skin protection creams, n (%)	658 (77.0)	694 (81.3)	854	0.025 ^e
Use of emollients, n (%)	726 (85.0)	777 (91.0)	854	<0.001 ^e
Use of protective gloves, n (%)	832 (95.8)	829 (95.5)	868	0.80 ^e
Confident in being able to remain in occupation, n (%)			861	<0.001 ^d
Yes	338 (39.3)	557 (64.7)		
Possibly yes	343 (39.8)	199 (23.1)		
No idea	138 (16.0)	41 (4.8)		
Possibly no	35 (4.1)	32 (3.7)		
No	7 (0.8)	32 (3.7)		

^aMean ± standard deviation.^bWithin the 12 months before the tertiary individual prevention programme (T1) versus average annual number in the second and third years of follow-up (T6).^cPaired *t*-test.^dWilcoxon signed-rank test.^eMcNemar test.

Similarly to the 1-year follow-up data (13), we observed a significant reduction in days of absence from work attributable to OSDs within the second and third years after discharge as compared with the year before the intervention. Previous calculations have shown that the annual societal cost for OSDs in Germany is €8799 per patient (7), and that most of this cost comprises indirect costs related to work absenteeism and loss of productivity. Thus, the observed reduction in days of absence from work after the TIP decreases the overall cost related to OSDs considerably. The TIP is financed by the statutory accident insurance organization, which is funded solely from the employers' contributions. These are based on the expenditures of prior years. Thus, our results suggest that, despite initial investments, the TIP finally results in savings for the statutory accident insurance organization and thereby for the employers.

Three years after the TIP, the severity of OSD and the related quality of life were significantly improved as compared with on admission, indicating that the early improvements (12, 13) were largely sustained over the years. Notably, these improvements were unchanged in the subgroup of those still working in the same occupational field, which indicates that, after the TIP, most patients are able to continue working, with markedly

improved OSDs and quality of life. Complete healing of occupational skin lesions was found in approximately one-quarter of patients 3 years after the TIP, despite continuation of work. The use of glucocorticosteroids was significantly lower than before the TIP. This is most likely related to the decreased severity of OSDs. Moreover, the use of glucocorticosteroid-free topical treatment was promoted and initiated in most patients during the TIP, in view of the detrimental effects of long-term corticosteroid treatment on the skin barrier function, which may impair its capacity to protect against skin hazards at the workplace (23, 24). This is in accordance with the German guideline on the management of HE (25).

The health education was well accepted. It resulted in improved and sustained preventive and protective behaviour at work. Those who were still working in the same occupational field 3 years after the TIP reported a significantly lower frequency of hand washing, indicating primarily a reduction in soiling resulting from improved protective measures. At the same time, the self-reported frequency of hand disinfection increased. The use of hand disinfectants was, in particular, promoted in healthcare workers during the TIP, to limit the detrimental effects of hand washing (26). Similarly, the rate of those using

protective creams and emollients rose significantly, in accordance with the aim of the health education. Owing to the stepwise intervention approach towards OSDs in Germany, many of the patients had already received advice regarding the use of protective gloves prior to the TIP as part of previous primary and secondary prevention measures. Thus, the use of protective gloves was already high at admission (95.5%), and did not change significantly thereafter. However, during the TIP, the patients were instructed on how to use protective gloves correctly, including how to remove them safely. Moreover, the protective gloves provided at the individual workplace were evaluated and replaced by alternative gloves if necessary, taking into account workplace exposures and contact allergies to glove components diagnosed in the meantime. Thus, even though the proportion of those claiming to use protective gloves at work did not change, counselling during the TIP probably improved the protective effect of gloves by better selection and usage.

To our knowledge, the TIP is a unique intervention for severe OSD, with no comparable equivalents in other countries so far. It is well established in Germany, and is supported by the national social insurance system with its independent statutory accident insurance organizations. These put a strong focus on the prevention of occupational diseases (10). As discussed previously, a randomized study design would have been desirable, but, for ethical and legal reasons, no control group was feasible (12, 13). To our knowledge, this is the largest well-documented and prospectively studied intervention cohort of patients with severe OSD. The follow-up over a period of 3 years with a low drop-out rate provides reliable data on the long-term effects of the TIP. We believe that different elements of the TIP are crucial for its success. They cannot be evaluated separately. In more

than one-third of patients, diagnostics during the TIP showed contact allergy that had not been detected before, and resulted in specific preventive measures at the workplace. Moreover, the dermatological treatment was modified in many patients. The health education probably led to increased compliance and adherence with regard to the preventive strategies. This is supported by another study indicating that health education in patients with OSDs improves the long-term prognosis regarding remaining in the workforce (27). In addition, other factors probably contributed to the beneficial effects of the TIP, especially the involvement of local dermatologists and employers. The TIP has become a well-established part of the stepwise approach for managing patients with OSDs in Germany. The presented data show its high value for patients with recalcitrant OSDs in reducing disease severity, and improving ability to work, quality of life, and prognosis. Another benefit of the TIP is the detailed information provided by the TIP centres, which allows for swift and competent case management by the statutory accident insurance organizations. In the few cases in which the TIP fails to prevent the recurrence of severe OSDs after return to work, the medico-legal evaluation is simplified, as it has been proven that all available preventive means to keep the individual at the workplace have been exhausted.

In conclusion, the data of the 3-year follow-up show the sustainability of the previously reported positive effects of the TIP, and indicate its value in managing patients with refractory OSDs by reducing the burden of disease and improving their chances of remaining in the workforce. Despite all efforts, hairdressers with severe OSD taking part in the TIP have the highest risk of leaving their occupation afterwards.

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