

First results from the multicentre study Rehabilitation of Occupational Skin Diseases – Optimization and Quality Assurance of Inpatient Management (ROQ)

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Summary

Background and objectives. The German stepwise procedure of handling occupational skin diseases (OSDs) offers interdisciplinary integrated (inpatient/outpatient) rehabilitation measures [tertiary individual prevention (TIP)] for severe OSD. In 2005, a prospective cohort multicentre study was started in order to evaluate TIP.

Methods. One thousand seven hundred and eighty-eight patients with severe OSD were treated and educated in five clinics with follow-up before and 4 weeks after return to work.

Results. During the inpatient phase, there was a significant improvement in the severity of OSD (Osnabrueck Hand Eczema Severity Index, $p < 0.001$) and in the quality of life (Dermatology Life Quality Index, $p < 0.001$). These effects were largely sustained during the outpatient follow-up phase and in the 4 weeks after return to work. Among all patients, 89.4% used topical steroids before TIP, including 52.5% using high-grade topical steroids; 93.2% of the patients were able to refrain from using topical steroids before returning to work. As a result of TIP, return to work was possible for 1587 patients (88.8%).

Conclusions. The primary objectives of TIP (return to work, improvement of OSD, enhancement of quality of life, and reduction in the use of topical steroids) were successfully met. The long-term follow-up (1 and 3 years after TIP) will examine whether these favourable outcomes can be sustained.

Key words: hand eczema; inpatient/outpatient rehabilitation programme; occupational skin diseases; patient education; tertiary individual prevention.

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Occupational skin diseases (OSDs) have long been by far the most frequent of all reported occupational diseases in Germany. For example, in 2005 (start of the study), 16 473 (28.3%) of the total of 58 114 cases reported to Statutory Accident Insurance (SAI) in Germany concerned OSDs (1). This is relative to the total of 42 million workers insured, equalling 30 million full-time positions. It is assumed that OSDs are under-reported by a factor of 30–50 (2). In Germany, patients with OSDs are obligatorily insured by SAI. OSDs account for almost 60% of the total annual cost of occupational rehabilitation covered by SAI in Germany. The annual economic costs resulting from OSDs (including absence from work and loss of productivity) in Germany are estimated as being up to €1.8 billion (1, 3). The SAI bodies are legally obliged by the German Social Security Code to take all measures necessary to prevent accidents, occupational diseases, and work-related health risks (4, 5).

This emphasizes the need for specific, early secondary prevention of OSD (6–12), and also the need to create options to help affected individuals, where secondary prevention measures are not successful or OSD has already become refractory (13, 14). Specific integrated interdisciplinary (inpatient/outpatient) rehabilitation measures [tertiary individual prevention (TIP)] have therefore been developed for these cases of severe OSD. On the basis of previous experience, including the Osnabrueck TIP-model (15, 16), the prospective multicentre study Rehabilitation of Occupational Skin Diseases – Optimization and Quality Assurance of Inpatient Management (ROQ) was initiated in 2005 with the goal of evaluating the efficacy, transferability and sustainability of TIP¹ (17).

Materials and Methods

ROQ was planned as an interventional study ($n = 1788$ consecutive patients) divided into different phases. Only patients with OSD resistant to outpatient therapy are included. As described by Skudlik et al., the study is divided into three phases (17).

The first phase is a 3-week inpatient period, with an interdisciplinary intervention programme including treatment, education, and counselling. In addition

to allergy and skin bioengineering diagnostic testing, stage-adapted dermatological therapy is performed, with steroid-free approaches being preferred. To increase motivation and modify knowledge, attitudes and behaviour with respect to the adequate use of skin protection at the patient's workplace, intensive healthcare instruction and psychological interventions are undertaken during the 3-week inpatient period (18, 19). The recommended skin protection measures are practised in simulated workplace models under the supervision of occupational therapists (synonym: ergotherapists) (19). As a supporting measure, a regular consultation with representatives of the SAI is offered to the patients, to discuss personal insurance and legal matters (20).

The second phase of treatment lasts for 3 weeks, during which the patient remains absent from work and receives outpatient treatment from a local dermatologist near his place of residence. This treatment is aimed at fully consolidating the epidermal barrier of affected skin areas.

To guarantee that these different interdisciplinary intervention measures can be implemented in a standardized fashion with equal quality at all centres, a detailed operation manual encompassing all structural, methodical and scientific aspects of TIP, regular 'train-the-trainer' schoolings and quality circles with all co-workers of all centres have been developed and implemented.

At the start (T1) and end (T2) of the 3-week inpatient stay, as well as at the end of the additional 3-week period after the inpatient stay (T3), standardized dermatological examinations are performed.

In the third phase, at the end of this 6-week period, the patients return to their workplaces, under continuous outpatient dermatological support and with the provision of optimized skin protective measures and optimized terms and conditions for work organization. The clinical course is then evaluated with another such standardized dermatological examination 4 weeks after the patient has returned to work (T4). The long-term success of the measures is examined by such standardized dermatological examinations after 1 year (T5) and 3 years (T6) (Fig. 1).

These measures are covered by SAI.

In order to achieve standardized and uniform documentation in all centres, modular data collection instruments were developed. The current clinical findings at the T1 up to T6 were recorded by using the Erlanger Atopy Score (21) and the Osnabrueck Hand Eczema Severity Index (OHSI) (22, 23), and classifying the severity grade of OSD in accordance with the recommendations for social legal evaluation of OSD in Germany [Bamberger Merkblatt (Bamberg Medical Bulletin)] (4). Internal, orthopaedic and neurological or psychiatric comorbidities were also documented. In addition, the patients' self-evaluations

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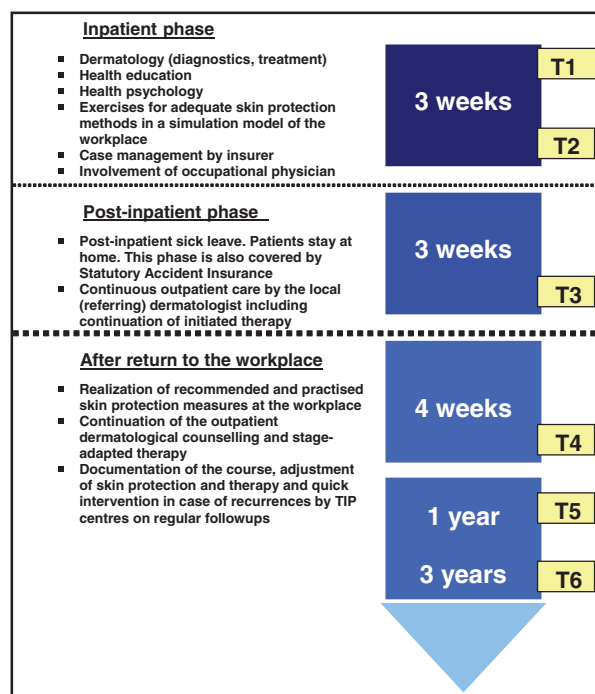


Fig. 1. Flow chart of the tertiary individual prevention (TIP) programme regarding the multicentre study 'Rehabilitation of Occupational Skin Diseases – Optimization and Quality Assurance of Inpatient Management (ROQ)'.

of OSD, motivation and quality of life [Dermatology Life Quality Index (DLQI); Life Quality Index Occupational Dermatoses (LIOD)] (24, 25) were collected. Important information on occupational activities, individual skin protection, occupational burdens, the disease course before inpatient therapy and legal and insurance aspects were also documented.

Recruitment took place between 22 November 2005 and 31 December 2009, and follow-up is being continued. This work deals only with the results of the examinations at T1–T4.

The study has been approved by the ethics committees of the institutions involved, and has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. All patients gave their informed consent prior to their inclusion in the study.

Results

Characteristics of the intervention group/occupations/follow-up/return to work

The sex ratio of the consecutive patients ($n = 1788$) was nearly 1:1. The patients included all occupations with skin

Table 1. Demographic data of the study participants

	Total	Male (%)	Female (%)
Participants	1788	881 (49.3)	907 (50.7)
	Mean	Range	
Age (years)	43.2	17–67	
Profession, no. (%)			
Healthcare	526 (29.4)		
Metal Industry	490 (27.4)		
Hairdressing	180 (10.1)		
Building	158 (8.8)		
Food handling	111 (6.2)		
Cleaning	81 (4.5)		
Chemical Industry	63 (3.5)		
Others	179 (10.0%)		

risks, but most patients were from the areas of 'healthcare' or 'metal' (Table 1). The course of the project between T1 and T4 is shown in Fig. 2. Sixty-nine patients dropped out of the study up to T4, corresponding to a drop-out rate of 3.9%. The main objective of the study was return of the patients to their jobs, and this was achieved for 1587 (88.8%) patients. An examination was then performed 4 weeks after return to work (Fig. 2).

Wet work was a frequent occupational hazard in all occupational groups. Wet work was defined according to the German technical regulations on hazardous substances (TRGS 401) as more than a total of 2-hr of exposure of skin to humid environments or impermeable gloves (26). Two hours or more of wet work was reported particularly often by the hairdressers (96.7%), followed by the 'cleaning' group (91.4%), the 'food-handlers' group (87.4%), and the 'healthcare' group (82.1%) (Fig. 3). The proportion of 'soiling of the hands during work' varied between the occupational groups. Soiling of hands was defined according to a recently published study that characterized soiling severity criteria (27). Particularly high proportions of 2-hr or more of soiling of the hands at work were found in the 'construction workers' group (71.5%) and the 'metal' group (58.6%) (Fig. 4). In the 'food' group, 41.4% reported that they washed their hands 10–20 times daily and 27.0% more than 20 times daily (Fig. 5).

Clinical findings and therapy

One thousand six hundred and seventy (93.4%) of all diagnoses were for hand eczema. One thousand three hundred and fifty-seven (81.3%) of the hand eczema patients had an irritant component of the dermatosis, 918 (55.0%) an atopic component, and 662 (39.6%) an allergic component. There were many cases of aetiological overlap and combined diagnoses (Fig. 6).

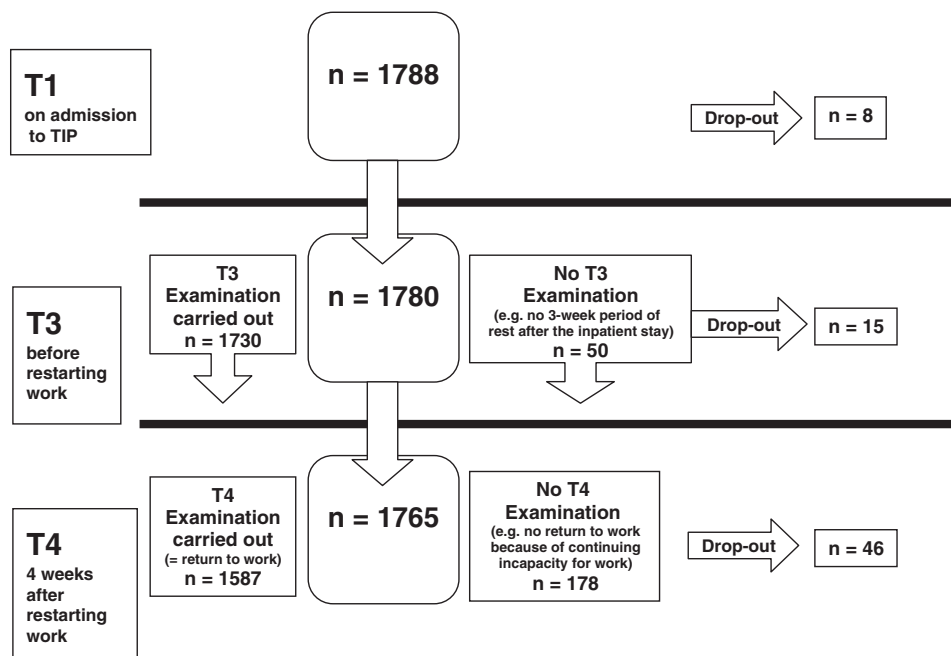


Fig. 2. ‘Rehabilitation of Occupational Skin Diseases – Optimization and Quality Assurance of Inpatient Management’ cohort T1–T4, drop-outs. TIP, tertiary individual prevention.

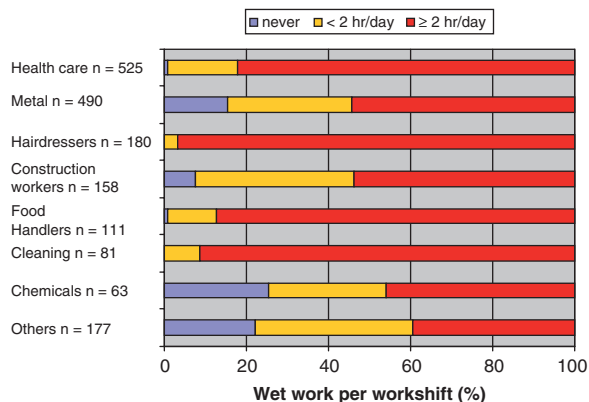


Fig. 3. Proportion of wet work in the different occupations.

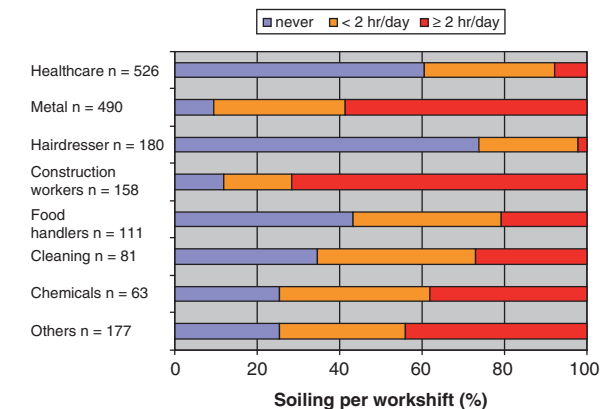


Fig. 4. Proportion of soiling of the hands during work in the different occupations.

In 118 of 1788 cases (6.6%), no hand eczema was diagnosed. Most of these patients ($n = 100$, 5.6%) were diagnosed as having psoriasis of the hands (publication in preparation).

Only 10.6% of the patients did not use topical steroids in the year before TIP. Most patients (89.4%) used topical steroids before TIP, including 922 of 1756 patients (52.5%) who used potent grade 3 or grade 4 topical steroids, mostly at regular intervals (Fig. 7). As planned in the concept of TIP therapy, the proportion of steroid-free therapy was successfully increased to 1497

of 1788 patients (83.7%) by the end of the inpatient phase. This proportion was further increased to 1599 of 1716 patients (93.2%) by the end of the post-inpatient phase. Four weeks after return to work, the proportion of steroid-free treatment was 1250 of 1537 patients (81.3%).

Between T1 and T2, there was a highly significant improvement in the severity of the inflammation of the skin of the hands ($p < 0.001$; from 6.3 to 2.8). This effect was stable up to T3. Four weeks after return to work, the

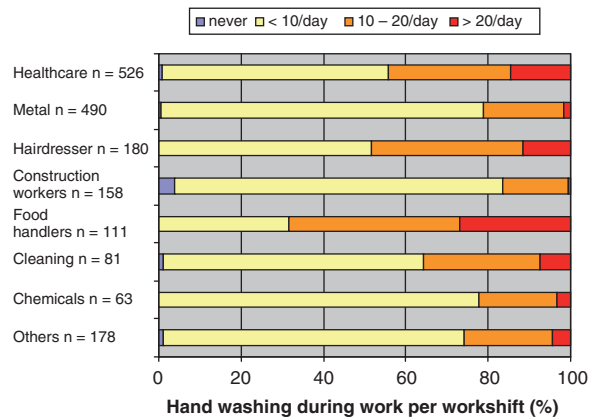


Fig. 5. Frequency of hand washing during work in the different occupations.

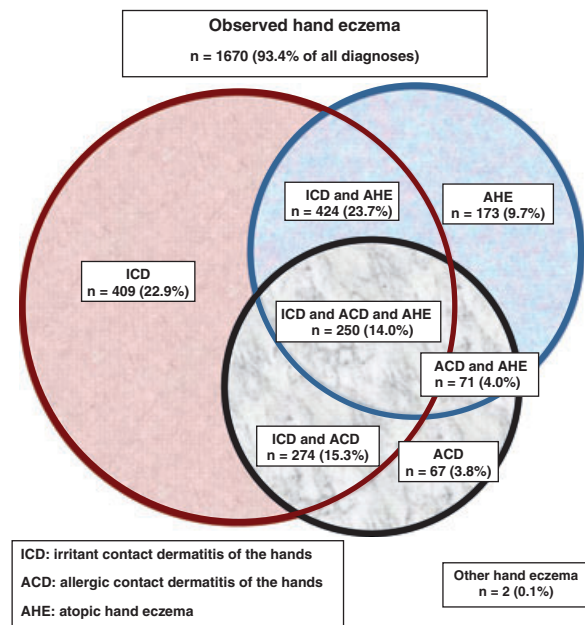


Fig. 6. Aetiological classification of observed hand eczema.

OHSI score came to 3.7 points, corresponding to a slight deterioration (Fig. 8).

Quality of life

In agreement with the clinical findings, there was also a highly significant ($p < 0.001$) improvement in DLQI score between T1 (10.4 points) and T2 (5.5 points). This value was also stable up to T3 (5.4), but had slightly deteriorated by T4, with 6.9 points (Fig. 9). It is not helpful to use LIOD to determine the quality of life up to

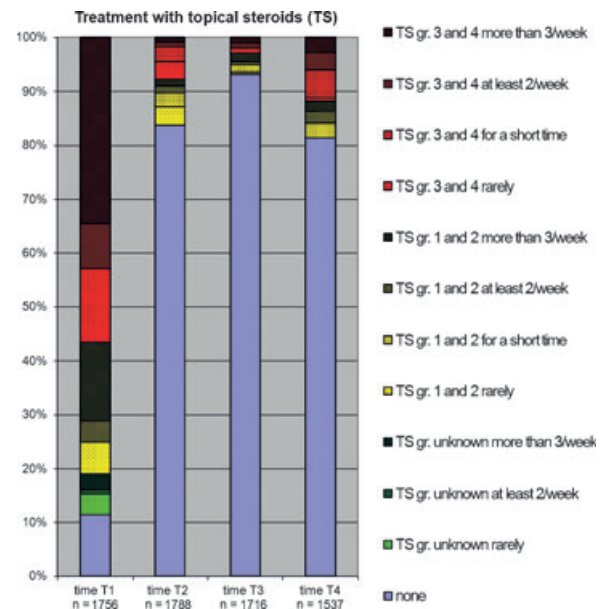


Fig. 7. Grade of topical steroids (TS) used and frequency of treatment at the examination time points T1, T2, T3, and T4, gr. grade.

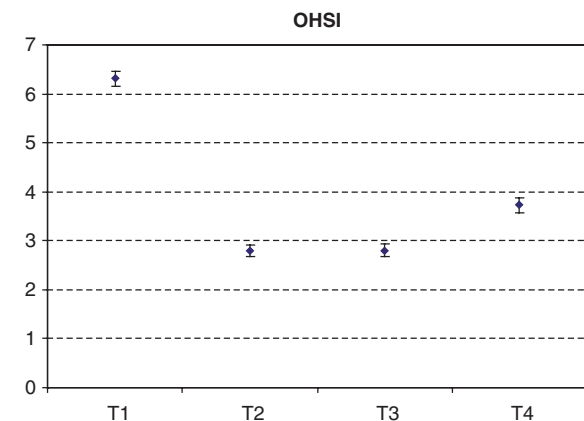


Fig. 8. Osnabrueck Hand Eczema Severity Index (OHSI) (95% confidence intervals of the mean OHSI score) at the examination time points T1 (n = 1788), T2 (n = 1788), T3 (n = 1730), and T4 (n = 1584).

T4, as it is based on 3-month intervals. Future evaluations will include time points T5 and T6, and DLQI and LIOD will be evaluated in parallel.

Discussion

The present report describes the performance of the 3-year follow-up multicentre study, and deals exclusively with the results of the examination at T1 up to T4 (in a regular

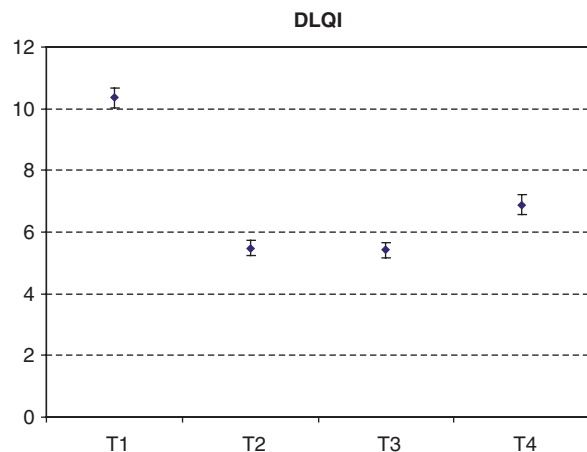


Fig. 9. Dermatology Life Quality Index (DLQI) (95% confidence intervals of the mean DLQI score) at the examination time points T1 (n = 1643), T2 (n = 1544), T3 (n = 1621), and T4 (n = 1507).

case, this means the first 10-week period after hospital admission).

Follow-up of the cohort up to T4 was successful, and the drop-out rate was satisfactorily low. The primary study objective of 'return to work' was achieved for almost 90% of patients. Future evaluation up to T5 (1-year follow-up) and T6 (3-year follow-up) will be decisive for the assessment of the long-term effects of TIP. A previous study using a questionnaire showed that 66% of TIP patients had remained at work over a 1-year period after admission to TIP (n = 1164) (16).

As expected, the predominant diagnosis was hand eczema. If conclusions on the risk factors and prognosis are to be reached in the future, including the additional long-term follow-up, it will be desirable to evaluate the different aetiologies of hand eczema. The problem here is that there is no generally accepted classification system for hand eczema. In the present study, we have employed a classification system based on a recently published concept (28). This considers various aetiological subdiagnoses of hand eczema and their combinations. In the context of the secondary prevention of occupational dermatoses, irritant hand eczema is more frequent than allergic or atopic hand eczema (11, 29–32). On the other hand, a current questionnaire-based study with long-term follow-up of 7–14 years in 605 patients has found more allergic than irritant hand eczema (59% and 41%, respectively); however, no combination diagnoses were made, and the diagnosis of irritant hand eczema was excluded if work-related contact allergy had been shown (33). For our TIP cohort, we showed that combination diagnoses of irritant and/or allergic and/or atopic hand eczema were dominant (57%) in

patients with advanced occupational dermatoses. There was an irritant component in 81.3% of all patients with hand eczema. The above-mentioned variations in subdiagnoses of hand eczema agreed with the findings of a recent European cross-sectional multicentre study (n = 416 patients) (28). As hand eczema has a variety of causes, usually with a combination of exogenous and endogenous triggers, extensive diagnostic, therapeutic and educational management is necessary in the approach to advanced OSD, which is why all of these components have been implemented in TIP (1, 34).

The primary therapeutic objectives for the inpatient phase and the post-inpatient phase, from T1 to T4, were successfully achieved. There was a significant reduction in the severity of the skin disease up to the time of restarting work. It was possible largely to avoid topical steroids. It is known that epidermal barrier homeostasis is affected by the regular use of highly potent topical steroids, thus enhancing skin irritability and reducing the options for successful implementation of improved skin protection and care (35–38). Considering recent findings of steroid effects on barrier properties, concomitant exposure to irritants at the workplace and to topical steroids seems to be detrimental. On referral, most patients in our TIP cohort initially used highly potent topical steroids, but, in most cases, they could be replaced with steroid-free therapy and, in more than 80% of patients, this could be continued when work was restarted. This parameter will be evaluated at T5 and T6, in order to assess the long-term sustainability of TIP.

As regards the shortcomings of this study, a randomized study design would have been desirable in principle (39, 40). However, a randomized study design cannot be implemented under the conditions of the interdisciplinary integrated (inpatient/outpatient) rehabilitation measures for OSD in Germany: The patients included in the study are all insured by SAI in Germany, as is every worker in the country. As the German Social Security Code rules that SAI must ensure the prevention of occupational diseases by all suitable means (1, 4, 5), they were legally entitled to such measures. Therefore, no control group was possible. In addition, it would be unethical to deprive patients of such preventive measures, because of the already existing positive findings of previous investigations (15, 16).

To our knowledge, this is the largest such well-documented intervention cohort of patients with severe OSD; it is to be expected that the continuing long-term evaluation of the follow-ups will provide further reliable data on the sustainability of such preventive measures, as this will include a very detailed recording of parameters relevant to ROQ, including occupation, sick leave periods resulting from to OSD, and therapy (particularly with

topical steroids), covering the period up to 1 year before participation in TIP and the long-term follow-up for 3 years. The extremely low drop-out rate will contribute to the reliability of the data.

At present, on the basis of the results obtained, it can be assumed that TIP can be readily incorporated into the concept of hierarchically graded medical and educational management of OSD, adapted to the individual severity of the condition (17, 19, 34). Healthcare professionals

in other countries are aware of the successful TIP concept. In Australia, it has been proposed that the 'German model' should be utilized to institute an educational and rehabilitative programme concerning severe OSD (41). The ultimate goal is the creation of good practice models tailored to meet the needs and specificities of the various occupational settings and social insurance systems in other countries, to achieve the best possible outcome for patients with severe OSD.

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