

## Appendix H: Evidence Tables – Clinical Studies

### H.1 Self-management

#### H.1.1 Randomised controlled trials

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
N. J. Mork, J. Austad, and L. Brolund. An open, parallel groups, study of the importance of thoroughness of application in the treatment of psoriasis with a dithranol cream (Micanol). Acta	RCT  Single centre study, Norway  <ul style="list-style-type: none"> <li>• <b>Setting:</b> outpatient</li> <li>• <b>Randomised:</b> Unclear method.</li> <li>• <b>Washout period:</b> unclear</li> <li>• <b>Unblinded.</b></li> </ul>	N=29  <b>Drop-outs (don't complete the study):</b>  N =2  1 in each group due to irritation – week 4 and week 2 (classified	<p><b>Inclusion criteria</b></p> <p>Chronic, stable, plaque-type psoriasis; 4-14 plaques of <math>\geq 6\text{cm}^2</math>; severity of erythema and induration <math>\geq 2</math> on 0-3 scale and desquamation <math>\leq 1</math> (permitted to receive salicylic acid or urea ointment before the study to reach this score)</p> <p><b>Exclusion criteria</b></p> <p>None stated</p>	N=15  <b>Micanol plus additional education</b> (information about the importance of being thorough when rubbing the cream in to the lesions) – repeated at each follow-up visit  At the first visit the investigator applied	N=14  <b>Micanol plus standard information</b>	<b>Treatment duration:</b> 6 weeks (or until complete clearance [TSS = 0])	<b>Primary outcome:</b>  Total severity score (sum of desquamation, erythema and induration each on 0-3 scale divided by 3) – assessed at baseline weeks 2, 4 and 6	None stated
			<table border="1"> <tr> <td>Parameter</td> <td>Micanol (N=14)</td> <td>Micanol + info</td> </tr> </table>					
Parameter	Micanol (N=14)	Micanol + info						

Derm.Vener eol. Supplement um. 172:23-24, 1992. REF ID: MORK1992 A	<ul style="list-style-type: none"> <li>• <b>Allocation concealment</b> Not reported</li> <li>• <b>Sample size calculation</b> no.</li> <li>• <b>ITT analysis</b> unclear (may be ACA)</li> </ul> <p><b>Drop-outs/withdrawals.</b> N=2</p>	as treatment failures; all available data from these patients was included in analyses)			(n=15)	Micanol on one plaque to demonstrate correct application				
			<b>% male</b>	42.9%	46.7%					
			<b>Age (years )</b>	43.8±14.1 (28-78)	45.1±16.1 (25-79)					
			Duration of disease and body surface area affected were not different			<p><b>Both arms:</b></p> <p>Micanol 1% once daily, removed after 30 mins with water and mild soap</p> <p>Emollients were permitted during the study</p>				
<b>Effect Size</b>										
Outcomes										
<b>TSS</b>	<b>Micanol</b>	<b>Micanol + extra info</b>	<b>p-value</b>							
Baseline score	1.98	1.91								
% reduction at week 2	23% (1.52)	34% (1.26)								
% reduction at week 4	31% (1.37)	47% (1.01)								
% reduction at week 6	39% (1.21)	67% (0.63)	<0.05							

**Author's conclusion**

- Thoroughness of application is an important factor for rate of healing in short-contact dithranol treatment

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding																					
C. Gradwell, K. S. Thomas, J. S. English, and H. C. Williams. A randomized controlled trial of nurse follow-up clinics: do they help patients and do they free up consultants' time? Br.J.Dermatol. 147 (3):513-517, 2002. REF ID: GRADWELL	<p>RCT</p> <p>Single centre study, UK</p> <p>Recruited over a 3-month period and enrolled for 6 weeks</p> <ul style="list-style-type: none"> <li>• <b>Setting:</b> outpatient</li> <li>• <b>Randomised:</b> Computer-generated list with block size of 8 (stratified by diagnosis).</li> <li>• <b>Washout period:</b> N/A</li> </ul>	<p>N=66</p> <p><b>Note:</b> mixed population (psoriasis and eczema – 46% psoriasis)</p> <p><b>Drop-outs (don't complete the study):</b></p> <p>N =10</p> <p>5 in each group did</p>	<p><b>Inclusion criteria</b></p> <p>Newly referred patients aged ≥14 years with a diagnosis of psoriasis or eczema</p> <p><b>Exclusion criteria</b></p> <p>None stated</p>	<p>N=33</p> <p><b>Normal care plus session with dermatology nurse specialist</b></p> <p>20-min interview with dermatology nurse specialist in addition to initial consultation with dermatologist</p> <p>An appropriate teaching aid was selected per patient (demo/leaflet, video, touch-screen computer or verbal</p> <p>Information was given regarding the skin condition,</p>	<p>N=33</p> <p><b>Normal care</b></p> <p>Initial consultation and follow-up with a dermatologist</p>	<p>6 weeks</p>	<p><b>Primary outcome:</b></p> <p>Change in DLQI</p> <p><b>Other outcomes:</b></p> <p>Patient knowledge, number of consultations during follow-up</p>	Crookes Healthcare																					
			<table border="1"> <thead> <tr> <th>Parameter</th> <th>Usual (N=32)</th> <th>Usual + nurse (n=33)</th> </tr> </thead> <tbody> <tr> <td>% male</td> <td>47%</td> <td>39%</td> </tr> <tr> <td>Age (years)</td> <td>47.0±19.0</td> <td>31.8±15.7</td> </tr> <tr> <td><b>Diagnosis:</b></td> <td></td> <td></td> </tr> <tr> <td>Psoriasis</td> <td>47%</td> <td>45%</td> </tr> <tr> <td>Eczema</td> <td>53%</td> <td>49%</td> </tr> <tr> <td>Other</td> <td>0</td> <td>3%</td> </tr> </tbody> </table>						Parameter	Usual (N=32)	Usual + nurse (n=33)	% male	47%	39%	Age (years)	47.0±19.0	31.8±15.7	<b>Diagnosis:</b>			Psoriasis	47%	45%	Eczema	53%	49%	Other	0	3%
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<p>2002</p>	<ul style="list-style-type: none"> <li>• <b>Unblinded.</b></li> <li>• <b>Allocation concealment</b> sealed, numbered opaque envelopes</li> <li>• <b>Sample size calculation</b> no – pilot study (constrained by length of study)</li> <li>• <b>ITT analysis</b> yes for DLQI – following DLQI instructions for missing fields and LOCF for other missing values</li> </ul> <p>Participants with missing data at baseline were excluded from further analysis on that scale</p>	<p>not return the final questionnaire (in the control arm 2 of the 5 also had no baseline data)</p>	<p><b>Disease severity</b></p> <table border="1" data-bbox="857 188 1227 491"> <tr> <td>Mild</td> <td>6%</td> <td>24%</td> </tr> <tr> <td>Moderate</td> <td>59%</td> <td>30%</td> </tr> <tr> <td>Severe</td> <td>34%</td> <td>45%</td> </tr> </table>	Mild	6%	24%	Moderate	59%	30%	Severe	34%	45%	<p>Despite randomisation age and disease severity were notably different</p>	<p>treatment application (including how much and where), where to receive support and how to get repeat prescriptions</p> <p>Participants were also provided with an individualised booklet and treatment programme</p> <p>Instructions about the quantity were based on the finger-tip unit or corticosteroids and used a teaspoon estimate for emollients</p>				
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	<b>Drop-outs/withdrawals.</b> N=10						
<b>Effect Size</b>							
Outcomes							
<u>Quality of life</u>							
<b>DLQI</b>	<b>Baseline</b>	<b>Change at 6 weeks</b>	<b>Mean difference in change</b>	<b>95% CI</b>	<b>p-value</b>		
<b>Normal care (n=31)</b>	10.7	-2.9	0.27	-2.3 to 2.8	0.83		
<b>Normal care + nurse (n=31)</b>	10.1	-2.6					
<u>Treatment concordance/knowledge</u>							
<b>Numbers who adequately understood:</b>		<b>Normal care (n=28)</b>	<b>Normal care + nurse (n=28)</b>	<b>p-value</b>			
- <b>How much treatment to apply</b>		24/26 (92%)	28/28 (100%)	0.23			
- <b>How long to apply for</b>		23/27 (85%)	28/28 (100%)	0.05			
- <b>How to obtain a repeat prescription</b>		14/24 (58%)	25/28 (89%)	0.01			
- <b>Where to get support</b>		14/26 (54%)	26/27 (96%)	<0.001			

**Note:** numbers vary for individual questions because of missing values

**Impact on service use**

	<b>Normal care (n=28)</b>	<b>Normal care + nurse (n=28)</b>	<b>p-value</b>
<b>% follow-up appointments with dermatologist cancelled because nurse could perform the assessment</b>	0%	33%	
<b>Visited GP during 6-wk follow-up</b>	11 (39%)	3 (11%)	0.01

**Author's conclusion**

- Dermatology nurses can add to a dermatology consultation and provide effective patient education and support in managing a skin condition.
- With this added service nurses could help to free up dermatologists' time, thus allowing them to see more new patients.
- Cost-effectiveness studies are now needed

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding																
<p>S. J. Ersser, F. C. Cowdell, P. G. Nicholls, S. M. Latter, and E. Healy. A pilot randomized controlled trial to examine the feasibility and efficacy of an educational nursing intervention to improve self-management practices in patients with mild-moderate psoriasis. J Eur Acad Dermatol Venereol, 2011. <b>REF ID:</b> ERSSER2011</p>	<p>RCT</p> <p>Multicentre study (8 centres), UK</p> <p>Conducted June and September 2009</p> <ul style="list-style-type: none"> <li>• <b>Setting:</b> primary care</li> <li>• <b>Randomised:</b> Cluster randomisation by toss of a coin (inadequate)</li> <li>• <b>Washout period:</b> N/A</li> </ul>	<p>N=64</p> <p><b>Drop-outs (don't complete the study):</b> N =5</p> <p>2 (7.1%) in experimental and 3 (8.3%) in control group</p> <p>Note: of those invited to participate (n=340) 53.2% did not respond and another 22.1% declined to participate of the 24.7% positive</p>	<p><b>Inclusion criteria</b></p> <p>Age ≥18 years, mild-moderate plaque psoriasis (currently using topical therapies only and having no contact with secondary care in 3 months before or after recruitment)</p> <p><b>Exclusion criteria</b></p> <p>None stated</p>	<p><b>N=28</b></p> <p><b>Normal care plus session with dermatology specialist nurse and education materials</b></p> <p>The intervention has three components: (i) structured, nurse-led group learning experience; (ii) supporting written and audiovisual material to provide additional information and a relaxation resource and</p>	<p><b>N=36</b></p> <p><b>Normal care</b></p> <p>Initial visit and follow-up for data collection only</p>	<p>6 weeks</p>	<p><b>Primary outcome:</b></p> <p>Change in DLQI</p> <p><b>Other outcomes:</b></p> <p>Change in PASI</p>	<p>Psoriasis Association</p>																
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<p>Effect Size</p> <p>Outcomes</p>												
<p><b>Full group</b></p>	<p><b>Intervention (n=26)</b></p>					<p><b>Control (n=33)</b></p>					<p><b>95% CI</b></p>	<p><b>p-value</b></p>

	<b>Baseline</b>	<b>Final</b>	<b>Change</b>	<b>Baseline</b>	<b>Final</b>	<b>Change</b>		
Mean DLQI (SD)	4.86±5.14	4.58±5.05	0.28±2.16	4.18±3.91	3.70±3.71	0.48±3.02	-1.20 to 1.61	0.772
Mean PASI (SD)	2.34±2.66	1.78±1.62	0.56±1.42	3.22±2.26	2.82±2.20	0.40±1.06	-0.81 to 0.49	0.619
<b>Post-hoc subgroup analysis for those with moderate disease severity/impact</b>								
<b>Baseline DLQI or PASI &gt;6</b>	<b>Intervention (n=9)</b>			<b>Control (n=13)</b>			95% CI for change	<b>p-value</b>
	<b>Baseline</b>	<b>Final</b>	<b>Change</b>	<b>Baseline</b>	<b>Final</b>	<b>Change</b>		
Mean DLQI (SD)	9.56±5.96	9.22±5.14	0.33±2.50	7.15±4.34	5.62±4.11	1.54±3.93	-1.90 to 4.31	0.427
Mean PASI (SD)	4.61±3.33	3.17±1.67	1.44±2.06	4.75±2.68	4.14±2.60	0.62±1.30	-2.32 to 0.66	0.259
<b>Usefulness of intervention (n=26)</b>								
<b>Score</b>	<b>Group learning</b>		<b>DVD</b>	<b>Workbook</b>		<b>Telephone conversation</b>		
Not useful	3.8%		3.8%	3.8%		7.7%		
Moderately useful	30.8%		26.9%	38.5%		30.8%		
Very useful	65.4%		26.9%	57.7%		53.8%		
No response	0%		42.3%	0%		7.7%		
<b>Author's conclusion</b>								
<ul style="list-style-type: none"> <li>• This study highlights the feasibility of delivering a self-efficacy based educational intervention for people with mild-moderate psoriasis in primary care establishing the numbers and design required for an adequately powered multi-centred trial.</li> <li>• People with moderate disease severity may be most likely to benefit from this intervention.</li> </ul>								



REF ID: KERNICK20 00	<ul style="list-style-type: none"> <li>• <b>Allocation concealment</b> unclear</li> <li>• <b>Sample size calculation</b> yes</li> <li>• <b>ITT analysis</b> yes – assumption s not stated</li> </ul> Participants who did not attend the initial clinic visit were excluded from further analysis  <b>Drop-outs/withdrawals.</b> N=28	11 (24%) in the intervention group and 8 (15%) in the control group were lost to follow-up (4-month questionnaire was not completed); there were no differences in initial DLQI between these groups		9%	2%	support of patients, carers and families  The nurse was able to offer as many consultations over 4 months as she deemed necessary (GPs signed prescriptions as indicated by the nurse without seeing the patients)			itchiness, pustules, swelling, dryness, extent of rash and thickness of rash. Each was scored as mild (1) to very severe (5). The sum was used as the clinical score and ranged from 3-15	
			Previous consultant referral	48%	50%					
			DLQI (0-30)	6.1 ± 4.9	6.8 ± 5.0					
			Clinical score (3-15)	9.3 ± 2.9	8.4 ± 3.1					
			Euroqol (0-100)	69.2±20.8	62.5±23.1					
			Despite randomisation % male and disease severity were notably different							
<b>Effect Size</b>  Outcomes										

Note that the median number of clinic attendances was 2 and during the trial 2 patients saw the GP for eczema or psoriasis in the intervention group compared with 14 in the control group ( $p < 0.005$ )

### Quality of life

Outcome	Intervention group (n=46)		Control group (n=54)		Change (p-value)
	Entry	Completion	Entry	Completion	
DLQI	6.1 ±4.9	4.6 ±4.7	6.8 ±5.0	6.2 ±5.2	-1.5 vs -0.6 (NS)
Clinical score (0-15)	9.3 ±2.9	7.6 ±3.3	8.4 ±3.1	8.1 ±3.3	-1.7 vs -0.3 (<0.05)
Euroqol generic QoL (0-100)	62.9±20.8	68.4 ±20.8	62.5 ±23.1	65.1 ±23.8	+5.5 vs +2.6 (NS)

### Authors conclusion

- The study was underpowered to detect the change in DLQI (power calculation based on 50% reduction in DLQI based on nurse intervention) but the intervention did achieve a 25% reduction in DLQI
- Nurse intervention significantly reduced clinical burden

H.1.1.1 Cohort study

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding												
C. Renzi, Pietro C. Di, P. Gisondi, L. M. Chinni, M. Fazio, A. Ianni, and S. Tabolli. Insufficient knowledge among psoriasis patients can represent a barrier to participation in decision-making. Acta Derm.Venereol. 86 (6):528-534, 2006. REF ID: RENZI2006	<p>Cohort study (2 consecutive phases; initial control phase followed by later experimental phase)</p> <p>Single centre study, Italy (recruited in waiting rooms of out-patient clinic and at hospital admission)</p> <ul style="list-style-type: none"> <li>• <b>Setting:</b> outpatients and in-patients</li> <li>• <b>Representative</b></li> </ul>	<p>N=402</p> <p><b>Drop-outs (don't complete the study):</b></p> <p>N =0</p>	<p><b>Inclusion criteria</b></p> <p>Attending Istituto Dermatologico dell'Immacolata (IDI-IRCCS) for out-patient visit or in-patient admission for psoriasis</p>	<p>N=171 (87 out-patients and 84 in-patients)</p> <p><b>Decision board aid</b></p> <p>(Sept 2003-Jan 2004)</p> <p>Decision board designed using information from literature review by a group including one dermatologist, one internist, one medical epidemiologist and one physician specialized in public health and preventive medicine. The draft was then</p>	<p>N=231 (116 out-patients and 115 in-patients)</p> <p><b>Routine clinical practice</b></p> <p>(Jan-April 2004)</p>	Unclear	<p>Satisfaction with decision making process</p> <p>Overall satisfaction with care</p> <p>(outcomes were assessed using a modified version of validated questionnaires, which was piloted before the study and included 25</p>	Italian Ministry of Health												
			<p><b>Exclusion criteria</b></p> <p>age &lt; 18 years; having visited the clinic during the last 3 months, (to exclude those attending for a follow-up visit)</p>																	
			<table border="1"> <thead> <tr> <th>Parameter</th> <th>Routine (n=231)</th> <th>Decision board (n=171)</th> </tr> </thead> <tbody> <tr> <td>% male</td> <td>68%</td> <td>62%</td> </tr> <tr> <td>Age (years)</td> <td>45±15</td> <td>43±13</td> </tr> <tr> <td>Severity*:</td> <td colspan="2">Approximate values</td> </tr> </tbody> </table>						Parameter	Routine (n=231)	Decision board (n=171)	% male	68%	62%	Age (years)	45±15	43±13	Severity*:	Approximate values	
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	<p><b>population sample:</b> yes – consecutive (but high proportion of in-patients)</p> <p>• <b>Confounders accounted for:</b> no</p>		<p>Mild Moderate Severe</p>	<p>28% 53% 18%</p>		<p>discussed separately with five dermatologists and five patients and refined. The aim was to present all the important information on different treatment options in a simple easily comprehensible and visually clear manner.</p>			<p>questions)</p> <p>Note: 5 dermatologists visiting out-patients and 6 treating in-patients were included</p>	
			<p><b>Diagnosis:</b></p> <p>Diffuse CPP (&gt;10% BSA)</p> <p>Localised CPP (&lt;10% BSA)</p> <p>PsA</p>	<p>47.3% 36% 6.8%</p>	<p>42.9% 33.9% 10.7%</p>					

	<ul style="list-style-type: none"> <li>• <b>Minimal attrition bias:</b> N/A – patients and dermatologists completed questionnaire either at discharge or after the out-patient visit</li> <li>Response rate was 88% in control and 86% in intervention groups</li> <li>• <b>Outcomes adequately measured:</b> Yes</li> <li>• <b>Appropriate statistical analysis:</b> yes</li> </ul>		<p>*Based on a 5-point scale according to dermatologists answer to the following question “In your experience, among all patients you have seen with this condition, how severe is the patient’s condition”?</p> <p>Patient characteristics were not significantly different between the groups</p> <p>However, in- and out-patients differed significantly in severity of disease: the majority of outpatients had mild (44.6%) and moderate (40.9%) disease, compared with the majority of inpatients having moderate (65.0%) and severe (22.3%) disease (p &lt;0.001).</p>	<p>The revised decision-board was piloted among 30 patients and minor corrections were made</p> <p>The final version consisted of an A4-page printed on both sides separated in to topics, phototherapy and systemics.</p> <p>Possible side-effects of each treatment option were colour-coded, depending on whether they occur frequently, sometimes or rarely.</p> <p>Additional information that could influence treatment choices was also included</p>				
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**Effect Size**

Outcomes

Note that the proportion of patients in the control group wanting to be more involved in decision making was significantly higher among in-patients than out-patients (42.7% vs. 24.8%;  $p = 0.002$ ).

However, satisfaction with all aspects of doctor-patient communication in the control group was always significantly higher ( $p < 0.001$ ) for outpatients compared with inpatients, except for overall satisfaction

There was no significant differences between in-patients and out-patients among the decision-board group regarding the preferred role in decision making and aspects of doctor-patient communication, except that fewer in-patients were completely satisfied with the opportunity the had to express an opinion about treatment ( $p=0.002$ )

**Satisfaction**

Outcome	Control group (n=231)	Decision-board group (n=171)	p-value
<b>Satisfaction with decision-making</b>			
Wanted to be more involved	76 (33.0%)	59 (34.7%)	
Satisfied	146 (63.2%)	107 (62.6%)	
Wanted to be less involved	9 (3.8 %)	5 (2.7%)	0.823
<b>Opportunity to express opinion/doubts</b>			
Completely satisfied	107 (46.5%)	83 (48.7%)	
Fairly satisfied	63 (27.2%)	46 (26.9%)	
Not satisfied	34 (14.8%)	19 (10.9%)	

Had no doubts	27 (11.5%)	23 (13.5%)	0.707
<b>Information on treatment options</b>			
Completely satisfied	126 (54.7%)	98 (57.1%)	
Fairly satisfied	82 (35.4%)	61 (35.9%)	
Not satisfied	23 (9.9%)	12 (7.1%)	0.626
<b>Doctor considered patient's preferences</b>			
Very much	130 (56.2%)	96 (55.9%)	
Somewhat	43 (18.6%)	34 (19.6%)	
Very little/not at all	58 (25.2%)	96 (24.5%)	0.967
<b>Information on treatment side-effects</b>			
Completely satisfied	118 (51.0%)	42 (56.1%)	
Fairly satisfied	77 (33.2%)	62 (36.5%)	
Not satisfied	37 (15.9%)	13 (7.4%)	0.059
<b>Overall patient satisfaction with care</b>			
Completely satisfied	144 (62.5%)	114 (66.7%)	
Not completely satisfied	87 (37.5%)	57 (33.3%)	0.408
<b>Authors' conclusion</b>			
<ul style="list-style-type: none"> <li>• Satisfaction with specific aspects of doctor-patient communication was not significantly different between the control and the decision-board.</li> <li>• A higher proportion of patients were satisfied with information on treatment side-effects among the decision-board group compared with the control group (this reached borderline significance)</li> </ul>			