A behaviour change package to prevent hand dermatitis in nurse working in the National Health Service: results of a cluster randomised controlled trial.

Short title: SCIN (skin care intervention in nurses) trial: final results

I Madan^{1*}, V Parsons¹, G Ntani², D Coggon², A Wright³, JEnglish⁴, P McCrone⁵, J Smedley⁶, L Rushton⁷, C Murphy⁸, B Cookson⁹, H C Williams¹¹

- ¹ Occupational Health Service, Guy's and St Thomas NHS Foundation Trust & King's College London, London, UK
- ² MRC Lifecourse Epidemiology Unit, University of Southampton, Southampton, UK
- ³ Centre for Behaviour Change Department of Clinical, Educational and Health Psychology University College London, UK
- ⁴ Dermatology, Circle Nottingham NHS Treatment Centre, Nottingham, UK
- ⁵ Centre for the Economics of Mental and Physical Health, King's College London, London, UK
- ⁶ Occupational Health Service, University Hospital Southampton NHS Foundation Trust, Southampton, UK
- ⁷ Epidemiology and Biostatistics, Imperial College London, London, UK
- ⁸ King's Clinical Trial Unit, King's College London, London, UK
- ⁹ Medical Microbiology, University College London, London, UK
- ¹⁰ School of Nursing, Midwifery & Social Work, University of Manchester, Manchester, UK
- ¹¹ Centre of Evidence Based Dermatology, University of Nottingham, Nottingham, UK

Corresponding author:

Dr Ira Madan

Consultant and Honorary Reader in Occupational Medicine, Guy's and St Thomas' NHS Foundation Trust and King's College London. Occupational Health Service, Education Centre, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH Telephone: + 44 7791 599272 Email: Ira.madan@kcl.ac.uk

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What's already known about this topics?

- Nurses are at high risk of developing hand dermatitis.
- Educational interventions are only partially successful in preventing hand dermatitis in health care workers.

What does this study add?

• The nurse participants in our study had a high level of positive beliefs about good hand care; however this was not translated sufficiently into their behaviours even when they were

provided with access to a behaviour change programme and given ready access to hand moisturisers.

 The BCP intervention did not have significant effect on reducing the hand dermatitis among at-risk nurses.

Abstract

Background: Occupational hand dermatitis poses a serious risk for nurses.

Objectives: To evaluate the clinical and cost-effectiveness of a complex intervention in reducing the prevalence of hand dermatitis in nurses

Trial design: Cluster randomised controlled trial at 35 hospital trusts/health boards/universities in the United Kingdom.

Methods: Participants were (i) first year student nurses with a history of atopic conditions (ii) intensive care unit (ICU) nurses. Participants at intervention sites received access to a behaviour change programme plus moisturising creams. Participants at control sites received usual care. The primary outcome was the change of prevalent dermatitis at follow-up (adjusted for baseline dermatitis) in the intervention versus the control group. Randomisation was blinded to everyone bar the trials unit to ensure allocation concealment.

Results: 14 sites were allocated to the intervention arm and 21 to the control arm. 2,040 (69.5%) nurses consented to participate and were included in the intention-to-treat analysis. The baseline questionnaire was completed by 1,727 (87.4%) participants. 789 (91.6%) ICU nurses and 938 (84.0%) student nurses returned completed questionnaires. Of these, 994 (57.6%) had photographs taken at baseline and follow-up (12-15 months). When adjusted for baseline prevalence of dermatitis and follow-up interval the odds ratio (95% confidence interval) for hand dermatitis at follow-up in the intervention group relative to the controls were 0.72 (0.33-1.55) and 0.62 (0.35-1.10) for student and ICU nurses respectively.

Harm: None reported

Conclusion: There was insufficient evidence to conclude whether our intervention was effective in reducing hand dermatitis in our populations.

Trial registration: Current Controlled Trials ISRCTN53303171.

Introduction

Occupational hand dermatitis is a major hazard in nurses (point prevalence 18-30%). (1) It often develops in the first few years after joining the profession (1, 2), impairs quality of life and may lead to job loss. (3, 4) The prognosis for established hand dermatitis is poor (5). The high prevalence of irritant hand dermatitis in nurses is associated with frequent hand washing and wearing occlusive gloves. Nurses may develop allergic contact dermatitis caused by exposure to sensitisers (e.g. rubber components) in the workplace. (6) United Kingdom (UK) Practice guidelines (7) recommend regular application of emollients for prevention, although use of moisturising creams by nurses is low. (8, 9) Antibacterial hand rubs rather than handwashing with soap are recommended for hand cleansing when the hands are not visibly contaminated by body fluids. (10) Correct hand drying with paper towels after washing is essential.(11)

Evidence that hand dermatitis in nurses is reduced by interventions which incorporate the above measures (11-16), is limited by a lack of standardised methods, small study size or failure to address cost-effectiveness. (17) While the effectiveness of educational programmes and individual counselling to promote optimal hand care behaviours among healthcare workers have shown encouraging results (14, 16), their delivery in the field is challenging. Authors have called for high quality trials, using interventions based on psychological theory. (14, 16, 18) In a study of patients with occupational hand dermatitis receiving inpatient tertiary prevention, variables based on the theory of planned behaviour explained 30% of the variance in post-intervention behaviours to prevent dermatitis and 38% of the variance in intentions for preventive behaviours. (19)

To address continuing uncertainty about the clinical and cost-effectiveness of interventions designed to prevent hand dermatitis among nurses, we undertook a pragmatic trial of a behavioural change programme (BCP) aimed at improving adherence to preventive measures.

Methods

We conducted a cluster randomised controlled trial in National Health Service trusts/health boards/universities (sites) across Britain, with sites, or clusters of neighbouring sites, as the units of randomisation. The trial protocol has been described elsewhere. (20) Sites were eligible for inclusion if they had an occupational health (OH) service and either trained student nurses or had an adult or paediatric intensive care unit (ICU). They were randomly allocated to an intervention or control arm.

Participants

There were two groups: i) student nurses about to start their first clinical placement and who were at increased risk of hand dermatitis because of a history of atopic disease (history of eczema, hay fever, or asthma) or hand dermatitis; and ii) full-time ICU nurses who were at increased risk of hand dermatitis through workplace exposure. Informed written consent was obtained from all participants.

Intervention

The intervention comprised a BCP which targeted: appropriate use of gloves; washing hands with soap and water only when the hands were visibly soiled otherwise using antibacterial hand rubs (6); using moisturising cream before, during and after shifts (6, 21); and contacting OH early if hand dermatitis occurred. The BCP was supported by provision of a personal supply of hand moisturiser to student nurses and regular supply of moisturising creams on the ICU wards. The local OH service, control of infection team, and line management reinforced the messages on skin care. Participants in both trial arms received a leaflet on hand care. The BCP was based on the Theory of Planned Behaviour and written in plain English. (22) It aimed to change relevant attitudes, subjective norms, perceived behavioural control and intentions by providing written evidence-based information about health, social and environmental consequences of skin care behaviours coupled with illustrative pictures. Participants were asked to form implementation intentions for hand cream use and checking for dermatitis. The BCP was offered on line or as a hard copy (32-page magazine). It was made available to ICU nurse participants when recruitment at their site was complete, and to student nurse participants two weeks before starting their first clinical attachment. Participants at control sites were managed according to established best practice (provision of a leaflet about optimal hand care)(21).

Outcomes

The primary outcome was the change from baseline to follow-up in the point prevalence of photographically discernible hand dermatitis, as assessed by two dermatologists using a bespoke photographic assessment method. (23) Secondary outcomes were the: i) change in severity of hand dermatitis; ii) days lost from sickness absence and days of modified duties because of hand dermatitis per 100 days of nurse time; iii) change in beliefs about dermatitis prevention behaviours; iv) change in the reported frequency of: use of hand rubs for hand cleansing; handwashing with water; and use of moisturising creams; v) change in quality of life score (EQ-5D-5L) (24) vi) extent to which moisturiser provided for the intervention was used.

Sample size and statistical power

The sample size was based on the participation of 26 sites (clusters, with each site recruiting 40 students and 40 ICU nurses. The expected prevalence of hand dermatitis was 5% (baseline) and 25% (follow up) in student nurses and 25% (baseline) and 23% (follow up) in ICU nurses. We estimated an intraclass correlation coefficient of 0.05 and that 20% of participants would be lost to follow up. With these assumptions and a 5% level of statistical significance (two sided) the study would have approximately 89% power to detect a reduction in prevalence at follow-up in the intervention plus trusts to 10% in students nurses and 95% power to detect a reduction in prevalence to 10% at follow-up in ICU nurses.

Randomisation

Randomisation (by King's Clinical Trials Unit) was carried out in four blocks as a single step at the beginning of the study. The blocks were defined according to whether centres planned to recruit students, ICU nurses or both, and centre size. Allocation was confined to the Trials Unit until participants were recruited and completed the baseline questionnaire. For the intention-to-treat analysis, the date of entry into the study was the date of consent form signature. Intervention allocation was concealed from field workers until all of the participants at that site had been recruited. The trial statistician, methodologist, dermatologists and health economist remained blinded until after the primary analysis. All nurses who consented to participate were included in the intention-to-treat analysis.

Data collection

Outcome data were collected through questionnaires and standardised hand photographs (23) at baseline, and follow-up (ideally 12-15 months later). Participants who were unable to attend a clinic for hand photography, were asked to submit hand images using their mobile phones (selfies). Intervention site participants were sent an "intermediate" questionnaire after three months, which asked whether they had accessed the BCP, and if not, their reasons for not doing so.

Statistical analysis

Statistical analysis was carried out with Stata® version 12.1. (25) The primary analysis compared changes in photographically assessed dermatitis between the two study arms according to intention-to-treat, and was run separately for student and ICU nurses. It used logistic regression modelling (restricted to participants with complete data on all relevant variables), with hand dermatitis at follow-up as the outcome variable, and adjustment for the presence or absence of hand dermatitis at baseline. Final effect estimates adjusted also for follow-up interval (treated as a continuous variable). Effect estimates were summarised by odds ratios (OR's) and 95% confidence intervals (CI's) of intervention versus control groups.

Secondary analyses explored effects on health beliefs and preventive behaviours. Health beliefs were characterised by 25 variables (treated as continuous measures) with scores ranging from 1 to 5. The effects of the intervention were assessed using separate linear regression models with each of the 25 measures at follow-up as an outcome variable and adjustment for the corresponding measure at baseline together with follow-up interval. Preventive behaviours were quantified by ordinal variables, with scores for hand washing with soap and water, and use of hand rubs ranging from 1 to 4, and those for use of moisturisers from 1 to 6. In ICU nurses, the effects of the intervention on each behaviour were assessed by ordinal logistic regression, with the score at follow-up as the outcome variable and adjustment for the corresponding score at baseline together with follow-up interval. Student nurses had not started their first clinical placement when they entered the trial, so it was un-necessary to adjust for their behaviour at baseline.

To account for clustering by site, random intercept modelling was used in all analyses, except where the intra-class correlation coefficient (ICC) was negligible (approximately equal to 0). The main analysis was supplemented by three sensitivity analyses excluding participants: i) for whom information about dermatitis was based on selfies; ii) with a follow-up time <12 or >15 months; and iii) at two sites which recruited exceptionally high numbers of student nurses.

With respect to missing data, all analyses were restricted to participants with data on the relevant outcomes. The main adjusted analysis of the primary outcome (presence of dermatitis at follow-up) was further restricted to participants with complete data on all relevant independent variables. For the health economic analysis, we did not impute for missing data and instead conducted a complete case analysis.

Ethics

Approval was granted by the Health Research Authority- (reference: 13/LO/0981).

Results

Recruitment and randomisation of sites

Among 54 eligible sites, 10 declined to participate. The, remaining 44 were assigned to 38 clusters comprising one (33 clusters), two (4 clusters) or three (1 cluster) sites. The rationale was that geographical proximity risked "contamination" if students had placements at more than one site. Nineteen clusters were randomised to the intervention and 19 to the control arm. After randomisation (but before subject recruitment), nine sites (seven clusters) withdrew due to workload concerns. The final number of 31 clusters (35 individual sites was still sufficient for statistical power. (This was more than the number of sites which we originally planned to recruit into the trial (n=26 sites) therefore this reduction did not negatively effect the power of the

trial). Of those 31 clusters, 14 were randomised to the intervention, and 17 to the control arm. The three clusters which, comprised more than one site were all randomised to the control arm. Where the sites within these clusters recruited ICU nurses only or students only, the clusters were recorded twice on the consort diagram (figure 1).

Recruitment of individual participants

Participants were recruited between September 2015 and December 2016. The flow of participants through the study is illustrated in Figure 1. We screened 2,934 nurses for eligibility; 2,040 (69.5%) consented to participate and were included in the intention-to-treat analysis. The baseline questionnaire was completed by 1,727 participants (87.4% response rate) (789 student (91.6% response) and 938 ICU nurses (84.0% response). Of those, 994 (57.6%) had both baseline and follow-up photographs, and contributed to the primary outcome analyses. 1,045 (60.5%) completed the follow-up questionnaire, and were included in analyses of effects on health beliefs and behaviours. Among baseline questionnaire responders, the proportions providing hand photographs both at baseline and at follow-up were lower in the intervention than the control groups (52.3% and 64.6% respectively), as were the proportions who completed questionnaires at both time-points (55.0% and 67.9%).

Characteristics of participants

Table 1 summarises baseline characteristics of participants according to the extent of their participation. Among student and ICU nurses, demographic characteristics and the baseline prevalence of atopic history were similar between the intervention and control groups. There was no indication that the subsets of nurses, who were included in the analyses of dermatitis, and health beliefs and behaviours, were unrepresentative of all participants.

Uptake of BCP

Among 519 nurses at intervention sites who contributed to the analysis of effects on hand dermatitis, 383 (73.8%) completed the intermediate questionnaire, of whom 188 (49.1%) had accessed the BCP (42.8% of students, 53.2% of ICU nurses). However, we did not capture reliable data on the extent to which participants completed the BCP .The main reported reasons for not accessing the BCP were lack of time (38%) and forgetting (36%).

Effects on hand dermatitis

Hand dermatitis was assessed at two time points (follow-up interval 7 to 27 months, median 13.5 months). Among student nurses in the control group, its prevalence was 7% at baseline and increased to 12% at follow-up. In the intervention arm, prevalence decreased from 15.1% at baseline to 10.3% at follow-up. Clustering of the outcome among student nurses was low (ICC \approx 0). Therefore, the final model fitted was single level, with adjustment for dermatitis at baseline and follow-up interval.

Among ICU nurses, the baseline prevalence of dermatitis was 16.5% in both arms. Among controls it decreased to 13.8%, while in the intervention arm it decreased to 9.9%. For ICU nurses, we used a random intercept model to account for clustering by site. Estimated ICCs were 0.01 for the model adjusted only for baseline dermatitis, and 0.02 with additional adjustment for follow-up interval.

When the (intention-to-treat) analysis was repeated after excluding nurses who reported that they did not access the BCP intervention (per-protocol analysis), the change observed in objectively assessed dermatitis from baseline to follow-up was more pronounced.

The effects of the intervention using these models are summarised in Table 2. While all of the analyses suggested a small benefit from the intervention, none were statistically significant.

Effects on health beliefs

The analyses of effects on health beliefs included 394 students and 651 ICU nurses (follow-up interval 7.9 to 26.9 months, median 13.7 months).

Figure 2 summarises the effects of the intervention on 25 health belief scores, as estimated by random intercept or single level models (according to the ICC), adjusted for beliefs at baseline and follow-up interval. The intervention had little impact on beliefs in either group, although overall there was a weak tendency for less deterioration and/or greater improvement in the intervention versus the control arm.

Effects on health behaviours

Differences between the intervention and control arms in the frequency of preventive behaviours at follow-up were mostly non-significant when adjusted for follow-up interval and (only in ICU nurses) for the corresponding measure assessed at baseline (Table 3). An exception was the use of moisturisers by ICU nurses, which was higher in the intervention group (adjusted OR 1.59, 95% CI 1.18, 2.14).

Effects on other outcomes

Severity of dermatitis was dichotomised (cut-off point 3) (23). Scores of ≥ 3 indicated severe dermatitis. Only two participants had severe dermatitis at baseline and three at follow-up. As severe dermatitis was uncommon, it was not analysed further. Severity score was defined as the average score between two dermatologists who assessed photographs. It was challenging to provide counts of participants for each category of severity (almost clear/mild/moderate). For example, 14 participants scored 2.5. For these 14, one dermatologist assessed severity as mild and the other dermatologist as moderate. Similarly, 62 participants were scored 1.5, but one dermatologist assessed as almost clear and the other as mild.

There was no difference in quality of life scores between the trial arms at baseline or follow-up, nor for quality-adjusted life years during follow-up.

Sick leave for dermatitis was reported by five student and four ICU nurses in the intervention arm and four student and five ICU nurses in the control arm. For logistical reasons, we did not collect reliable data on supplies of moisturisers. The mean intervention costs were £14 for students and £13 for ICU nurses.

Sensitivity analyses

After excluding data from selfies, the pattern of changes in prevalence of hand dermatitis was similar to the main analysis. None of the differences between intervention and control was statistically significant.

Restricting to participants who were followed-up at 12-15 months, the prevalence of dermatitis among student nurses increased from baseline to follow-up in both arms of the study. Among ICU nurses, it decreased in both arms. In fully adjusted models, no differences between intervention and control groups reached statistical significance. After excluding two trusts (both intervention sites) with high recruitment of student nurses, the prevalence of dermatitis among students increased from baseline to follow-up in the control arm, and decreased in the intervention arm. Repeat of the main analyses with adjustment also for sex and age had no material impact on effect estimates.

Harms

No adverse events were reported during the study.

Discussion

This trial found no clear benefit from a BCP in reducing the prevalence of hand dermatitis among student or ICU nurses. There was no significant impact on participants' beliefs about preventive behaviours, although the intervention was associated with more frequent use of moisturising creams by ICU nurses. Possible

reasons for the lack of effect include the low prevalence of severe dermatitis, participants' high level of baseline beliefs about the importance of using hand moisturisers, and low uptake of the BCP. Face-to-face delivery of the intervention may have been more effective but is unlikely to be cost-effective.

Our bespoke method for assessing and grading dermatitis from photographs (23) reduced the potential for subjective variation between observers, and allowed joint assessment by two experienced dermatologists in difficult cases. Moreover, the assessment was conducted blind to trial arm allocation or timing of photographs.

Errors may have occurred in the reporting of health beliefs and behaviours. If subjects reported what they perceived as desirable answers, this could have biased effect estimates in favour of the intervention. However, little benefit was found. Lack of data on the extent to which participants completed all (or only part) of the BCP was a notable limitation with this study. The differential rates of recruitment across the clusters is likely to have decreased overall the power of the study.

Our finding that the intervention had little if any impact on the prevalence of dermatitis concurs with recently published randomised trials (26-28), but should not be construed as evidence against the efficacy of preventive measures including reduced hand-washing and frequent use of moisturising creams. Although changes in the prevalence of dermatitis were not statistically significant, they were in the direction that might have been expected. Caution is warranted when interpreting the findings, generalisability, and potential benefits of the intervention, since the two study groups were specifically selected for high risk of hand dermatitis. It is possible the BCP was ineffective in high risk populations, but might be effective in nurses who are at lower risk. The components of our intervention are supported by evidence, appear to have no adverse effects and are relatively inexpensive. Therefore, these principles should continue to underpin strategies for preventing hand dermatitis in nurses. Healthcare employers should provide nurses with ready access to hand creams and rubs, but BCPs of the type we tested add little to best practice, and should not be adopted without further supportive evidence.

Trial registration ISRCTN number 53303171 Date of registration 21 June 2013.

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Stakeholder involvement

The patient involvement in this study differs from other studies in that the 'patients' are NHS nurses. During the set-up and conduct of the trial, the research team actively consulted with representatives from the nursing (including student) profession.

Contribution statement

Ira Madan: chief investigator
Vaughan Parsons: trial manager
Georgia Ntani: trial statistician.
David Coggon: trial methodologist

Alison Wright: behavioural science expertise

John English: occupational dermatology expertise. Assessment of hand photographs

Paul McCrone: health economics expertise

Julia Smedley: occupational health and recruitment expertise

Lesley Ruston: occupational epidemiology expertise

Caroline Murphy: Clinical trials expertise and governance

Barry Cookson: infection control expertise

Hywel Williams: clinical dermatology and trial expertise. Assessment of hand photographs.

All co-investigators provided input into the development of the protocol, management of the trial and interpretation of the findings. All co-investigators contributed to the production of the final manuscript.

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Table 1 Characteristics of nurses according to level of participation

	Completed baseline questionnaire		Hand photogo baseline and		Completed questionnaire both at baseline and at follow-up			
	Intervention	Control	Intervention	Control	Intervention	Control		
Student nurses								
Number	539	250	185	142	238	156		
Number (%) female	510 (94.6)	233 (93.2)	175 (94.6)	134 (94.4)	227 (95.4)	147 (94.2)		
Median age (IQR) in years ^a	21 (19-26)	22 (19-29)	23 (19-28)	23 (19-30)	22 (19-27)	24 (19-29)		
Number (%) with atopy ^c	531 (98.5)	238 (95.2)	181 (97.8)	135 (95.1)	233 (97.9)	148 (94.9)		
Number (%) with history of atopic dermatitis	145 (26.9)	65 (26.0)	51 (27.6)	39 (27.5)	61 (25.6)	45 (28.8)		
ICU nurses								
Number	453	485	334	333	308	343		
Number (%) female	388 (85.7)	410 (84.5)	285 (85.3)	278 (83.5)	266 (86.4)	286 (83.4)		
Median age (IQR) in years ^a	36 (27-45)	36 (27-45)	37 (28-45)	38 (28-46)	38 (28.5-47)	38 (28-46)		
Mean (standard deviation) hours worked per week ^b	36.7 (2.6)	36.7 (2.6)	36.6 (2.5)	36.7 (2.8)	36.5 (2.5)	36.7 (2.8)		
Number (%) with atopy	282 (62.3)	289 (59.6)	206 (61.7)	204 (61.3)	185 (60.1)	206 (60.1)		
Number (%) with history of atopic dermatitis	58 (12.8)	63 (13.0)	45 (13.5)	40 (12.0)	42 (13.6)	36 (10.5)		

^aData on age were missing for 10 student nurses (all in the control group) and 7 ICU nurses (1 intervention and 6 control).

^bData on hours worked per week were missing for 9 ICU nurses (4 intervention and 5 control)

^c Although all student nurses were screened for atopy by the occupational health team, not all reported atopic symptoms on the questionnaire

Table 2 Estimated effect of intervention on photographically diagnosed hand dermatitis

	Control Intervention							Estimated effect of intervention								
	Number assessed					Number assessed	Hand dermatitis at baseline		Hand dermatitis at follow-up		N	^a OR	(95%CI)	N	^b OR	(95%CI)
		N	(%)	N	(%)		N	(%)	N	(%)						
Student nurses	142	10	(7.0)	17	(12.0)	185	28	(15.1)	19	(10.3)	327	0.67	(0.32,1.39)	320	0.72	(0.33,1.55)
ICU nurses	333	55	(16.5)	46	(13.8)	334	55	(16.5)	33	(9.9)	667	0.65	(0.39,1.11)	647	0.62	(0.35,1.10)

^aOdds ratio (95% confidence interval) for prevalent hand dermatitis at follow-up in the intervention relative to the control group adjusted for baseline prevalence of dermatitis

^bOdds ratio (95% confidence interval) for prevalent hand dermatitis at follow-up in the intervention relative to the control group, adjusted for baseline prevalence of dermatitis and follow-up interval

Table 3 Estimated effect of intervention on frequency of preventive behaviours

Behaviour	•	ses) for level of same at baseline	^a Adjusted for follow-up interval and (in ICU nurses) level of same behaviour at baseline			
	^b Number analysed	°OR	(95%CI)	^b Number analysed	°OR	(95%CI)
Student nurses						
Hand-washing with soap and water	392	0.81	(0.47,1.39)	384	0.83	(0.48,1.43)
Use of hand-rubs	393	1.37	(0.95,1.98)	385	1.43	(0.97,2.09)
Use of moisturising cream before shifts	394	1.14	(0.79,1.63)	386	1.22	(0.84,1.77)
Use of moisturising cream during shifts	394	1.32	(0.79,2.21)	386	1.33	(0.91,1.92)
Use of moisturising cream after shifts	394	1.35	(0.95,1.93)	386	1.37	(0.94,1.99)
ICU nurses						
Hand-washing with soap and water	645	0.81	(0.49,1.32)	605	0.85	(0.51,1.42)
Use of hand-rubs	643	1.3	(0.94,1.80)	603	1.31	(0.95,1.80)
Use of moisturising cream before shifts	644	1.25	(0.94,1.67)	604	1.22	(0.90,1.64)
Use of moisturising cream during shifts	644	1.7	(1.25,2.31)	604	1.59	(1.18,2.14)
Use of moisturising creams after shifts	645	1.31	(0.90,1.92)	605	1.27	(0.88,1.85)

^a No adjustment was applied for behaviours at baseline in student nurses since they had not yet started clinical work.

^b Data on specific behaviours at baseline and/or follow-up were missing for up to 10 student nurses and up to 48 ICU nurses.

[°] Odds ratios (with 95% confidence intervals) from ordinal regression. Values >1 indicate that relative to the control group, the behaviour was more frequent at follow-up in the intervention group.