

## STUDY PROTOCOL v20

**Project reference: 11/94/01**

**Title: A cluster randomised controlled trial of a behavioural change package to prevent hand dermatitis in nurses working in the National Health Service**

### Abbreviations:

BCP	Behavioural Change Programme
CEACs	Cost-Effectiveness Acceptability Curves
CLRN	Comprehensive Local Research Networks
CONSORT	Consolidated Standards of Reporting Trials
CTU	Clinical Trials Unit
HSE	Health and Safety Executive
HTA	Health Technology Assessment
ICERs	Incremental Cost-Effectiveness Ratios
ICU	Intensive Care Units
MRC	Medical Research Council
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
OH	Occupational Health
OHS	Occupational Health Service
OHSI	Osnabrueck hand eczema severity index
PI	Principal Investigator
QALYs	Quality-adjusted life years
RCN	Royal College of Nursing
RCT	Randomised Controlled Trial
TEWL	Trans Epidermal Water Loss
TPB	Theory of Planned Behaviour
UK CRC	UK Clinical Research Collaboration
WHO	World Health Organization

## **1.0 Summary of project plan**

### *Aims*

We will test the hypothesis that a behavioural change intervention to improve hand care, based on the theory of planned behaviour and implementation intentions, coupled with provision of hand moisturisers, can produce a clinically useful reduction in the occurrence of hand dermatitis when compared to standard care in at-risk nurses working in the National Health Service (NHS). Secondary aims will be to assess impacts on participants' beliefs and behaviour regarding hand care. In addition, we will assess the cost-effectiveness of the intervention in comparison with normal care.

### *Intervention*

As participants in both the 'intervention' and usual care sites will receive an intervention, the principal intervention will be known as intervention plus and the usual care will be known as 'intervention light'. Intervention plus will centre on a bespoke on-line behavioural change package (BCP). Members of the study team will develop this with expertise in dermatology, occupational medicine, nursing, and health psychology and care will be taken to ensure compatibility with current guidance on infection control. It will include advice: on when and when not to use gloves; on when to use antibacterial hand rubs; on when to use moisturising cream; and to contact OH early if hand dermatitis occurs. As part of the package, nurses will be asked to form implementation intentions for performing behaviours in their workplace. These will be recorded, and participants will subsequently be reminded of them and offered the opportunity to revise them. Provisions to encourage adherence, such as moisturising creams, will support the package. It will be actively reinforced over the course of the study by consistent messages on skin care from local OH and control of infection teams, and from line management.

### *Methods*

We will test the interventions in a cluster randomised controlled trial at 35 NHS hospital trusts/health boards/university occupational health departments ('sites'), focusing on two groups of staff: (i) student nurses who are about to start their first clinical placements, and are at increased risk of hand dermatitis from wet work because of a past history of atopic disease or hand eczema (17 sites) and (ii) nurses working in intensive care units (including special care baby unit (SCBU) nurses) who are at increased risk of hand dermatitis because of the nature of their work (30 sites)

Nurses at 'intervention light' sites will be managed according to what would currently be regarded as best practice, with provision of an advice leaflet about optimal hand care "Dermatitis: Occupational aspects of management. Evidence-based guidance for employees" (also provided to the intervention plus group, and developed by Health and Work Development Unit, Royal College of Physicians) and encouragement to contact their OH department early if hand dermatitis occurs. However, they will not receive the BCP or active reinforcement of its messages. Nor will they routinely be offered supplies of moisturising cream over and above what is already standard practice in their site.

The impact of the interventions will be evaluated from information collected by questionnaires, standardised photographs of hands/wrists (which will be assessed for the presence of dermatitis blind to other information about the participant). In addition, we will assemble relevant economic data for an analysis of costs and benefits, and collect information from various sources to evaluate processes.

Statistical analysis will be by multi-level regression modelling to allow for clustering by site, and will take account of the paired nature of before and after comparisons in individuals.

The principal outcome measure will be the difference between intervention plus and intervention light sites in the change in point prevalence of visible hand dermatitis from baseline to 12-15 months after the intervention as assessed by the study dermatologists.

Secondary outcome measures will include:

- The difference between intervention plus and intervention light sites in the change in the prevalence and severity of visible hand dermatitis from baseline to the end of follow-up as assessed by the study dermatologists
- Days lost from sickness absence and total number of days of modified duties because of hand dermatitis per 100 days per year of nurse time during the 12-months of follow-up as indicated in the study questionnaires
- The change from baseline to after completion of the BCP, and to the end of the 12-month follow-up in beliefs about dermatitis prevention behaviours.
- The change from the baseline to the end of follow-up in dermatitis prevention behaviours relevant to skin care.
- The change from baseline to the end of follow-up in quality of life score
- The use of moisturiser provided for the intervention (in terms of requests for further supplies by student nurses and orders for supplies of moisturisers by ICUs).

## **2.0 Background and rationale**

Occupational irritant hand dermatitis is a major risk in healthcare. In a recent study, the 1-year prevalence of self-reported hand dermatitis among healthcare workers in a Dutch university medical hospital was 24%, as compared with less than 10% in the general population (Thyssen, Johansen et al. 2010). Amongst healthcare workers, nurses are the group at highest risk of hand dermatitis, with an estimated point prevalence of 18- 30% (Skudlik, Dulon et al. 2009, Smit, Burdorf et al. 1993). Moreover, in a study of German geriatric nurses, two thirds of those who reported hand dermatitis stated that it had developed after they had joined the profession (Skudlik, Dulon et al. 2009). Consistent with this, among Korean nursing students, the prevalence of hand dermatitis increased from 7% in the first year to 23% in the fourth year of training (Smith, Choe et al. 2006). The costs of hand dermatitis to the individual and employer are high. It not only affects quality of life, but also can lead to loss of employment (Hutchings, Shum et al. 2001, Fowler, Ghosh et al. 2006). Once an individual has developed irritant hand dermatitis the prognosis is poor. In a 15-year follow-up study of a Swedish general population sample, about a third of those with hand dermatitis needed on-going medical treatment and 5% experienced long periods of sickness absence, loss or change of job, or ill-health retirement (Meding, Wrangsjö et al. 2005). Affected individuals may also experience negative psychosocial consequences, such as sleep disturbance and interference with leisure activities (Meding, Wrangsjö et al. 2005).

The high prevalence of hand dermatitis in nurses is attributed to frequent hand-washing and poor hand-drying techniques (WHO 2009). Current hand-cleansing policies in the NHS are driven by efforts to reduce colonisation and transmission of infections, and the emphasis is on frequent use of hand rubs before and after patient contact, and washing with soap and water if the hands are visibly soiled (WHO 2009). However, little attention is paid to prevention of hand dermatitis.

For a nurse who develops irritant hand dermatitis, the condition is likely to be aggravated by exposure to hand hygiene measures. The presence of hand dermatitis may discourage nurses from undertaking adequate hand decontamination due to discomfort or concern about exacerbating skin lesions. It is known that 50% of people with hand dermatitis are colonised with *S. Aureus* (Haslund, Bangsgaard et al. 2009), and although controversial, there is a theoretical risk that nurses with hand dermatitis infected by MRSA could transmit the infection to patients. Occupational health professionals often have to advise nurses with active dermatitis to refrain from work until the lesions are healed, as it is difficult for them to avoid frequent hand- washing unless they are redeployed to a non- clinical area.

Various measures might help to prevent hand dermatitis in nurses and reduce the problems that it causes.

### *Moisturisers*

Two systematic reviews of the management of occupational dermatitis (NHS Plus, Royal College of Physicians, Faculty of Occupational Medicine. 2009, Nicholson, Llewellyn 2010) have concluded that moisturisers contributed importantly to both prevention and treatment at work. A review by the former Occupational Health Clinical Effectiveness Unit (now Health and Work Development Unit) focussed on the evidence for managing established occupational dermatitis, as distinct from prevention (NHS Plus, Royal College of Physicians, Faculty of Occupational Medicine. 2009). The group found inconsistent evidence from two studies where moisturisers were used as part of a complex intervention in nurses (Held, Wolff et al. 2001, Held, Mygind et al. 2002), but concluded that there was sufficient evidence to recommend that skin care programmes should include the use of emollients.

Guidelines produced by the British Occupational Health Research Foundation (Nicholson, Llewellyn 2010) recommended that the regular application of emollients helps to prevent the development of occupational dermatitis, citing three high quality studies (Saary, Qureshi et al. 2005, Arbogast, Fendler et al. 2004, Winker, Salameh et al. 2009), including a systematic review (Saary, Qureshi et al. 2005) and two randomised controlled trials (RCT) (Arbogast, Fendler et al. 2004, Winker, Salameh et al. 2009). One RCT found an improvement in all outcomes, including clinical skin inspection. In the other, transepidermal water loss (TEWL) improved among construction workers who used pre-and after-work creams compared to controls, but there was no difference in clinically assessed skin condition (Winker, Salameh et al. 2009). Moisturisers also improved skin condition in workers with damaged skin (Graham, Nixon et al. 2005). More recent reviews have also concluded that there is some evidence to support the use of educational interventions that include moisturisers, but this came from a small number of workplace studies, and the authors strongly recommended that more large high quality RCTs in working groups were needed (van Gils, Boot et al. 2011, Bauer, Schmitt et al. 2010).

In the experience of the dermatologists and occupational health physicians in the research team, moisturisers are not widely used by healthcare workers in the UK. This anecdotal observation is supported by a study of nurses working in ICUs in Germany which found that only 15% of the 204 respondents reported that they applied moisturising creams after hand washing and only 2% after skin disinfection with hand rubs. Furthermore, 9% never applied skin care to their hands and 72% reported that they did not perform final skin care after the last hand wash of the day (Grosse-Schutte, Assadian et al. 2011).

### *Hand cleansing*

The use of antibacterial hand rubs with the addition of moisturisers for hand hygiene reduces the drying and cracking of the skin that commonly results from repeated hand cleansing with soap and water (Larson, Friedman et al. 1997, Pedersen, Held et al. 2005). In addition, antibacterial hand rubs are associated with increased hand hygiene compliance and reduced rates of nosocomial infection (Boyce, Pittet et al. 2002, WHO 2009).

### *Hand drying and glove use*

Proper drying of the hands after washing is pivotal to good hand hygiene and care, particularly as wet skin is more likely to facilitate the transmission of bacteria than dry skin. A recent review of hand drying processes (Huang, Ma et al. 2012), which included 12 studies, concluded that paper towels are superior to electric air dryers and therefore should be recommended in locations where hygiene is vital, such as clinical environments. This was supported by The Royal College of Nursing (Royal College of Nursing 2012) and the World Health Organization (WHO 2009).

Skin care programmes which incorporate measures of the type that have been described, have shown a beneficial effect in the prevention of hand dermatitis in healthcare workers (Held, Wolff et al. 2001, Held, Mygind et al. 2002, Loffler, Bruckner et al. 2006, Dulon, Pohrt et al. 2009). However, a recent systematic review suggested that educational programmes could benefit from being more strongly informed by psychological theory, since their success relies on employees adopting appropriate preventive and protective behaviours (van Gils, Boot et al. 2011). Psychological theory has proved useful in understanding the behavioural determinants of hand hygiene practices among healthcare professionals (Dyson 2011, WHO 2009), and so is likely to be useful also in the design of interventions to modify such practices. Moreover, a meta-analysis of internet-based behaviour change interventions found that more extensive use of theory was associated with significantly greater effects and, in particular, that internet interventions based on the Theory of Planned Behaviour (TPB) tended to have more substantial effects on behaviour (Webb, Joseph et al. 2010). One of the few studies applying psychological theory to the prevention of occupational hand dermatitis examined the TPB's ability to predict the behaviour of a sample of German patients with occupational hand dermatitis receiving an inpatient tertiary prevention programme. The TPB variables explained 30% of the variance in post-intervention dermatitis prevention behaviour and 38% of the variance in intentions for preventive behaviours (Matterne, Diepgen et al. 2011). Systematic review of relevant evidence shows that forming implementation intentions and specific plans about how, when and where health-promoting behaviours will be performed increases the likelihood of individuals acting on their positive intentions (Gollwitzer, Sheeran 2006). Furthermore, evidence suggests that reminding individuals of their implementation intentions can facilitate longer-term behaviour change (Soureti, Murray et al. 2011, Prestwich, Perugini et al. 2009).

Although there are good reasons to expect that well designed skin care programmes would be beneficial for nurses, their effectiveness and cost-effectiveness remain uncertain. Trials to date have been limited by size and the possibility that the control group was aware of the intervention (van der Meer, Boot et al. 2011), or by a failure to address cost-effectiveness (Ibler, Agner et al. 2010). There is a need for a pragmatic trial to evaluate the clinical and cost effectiveness of a behavioural change programme (BCP) to improve the compliance of nurses with measures to prevent occupational hand dermatitis.

### **3.0 Evidence explaining why this research is needed now**

A 2010 Cochrane review of interventions to prevent occupational hand dermatitis concluded there was insufficient evidence for the effectiveness of most of the interventions used in occupational irritant hand dermatitis and that larger, well-designed randomised controlled trials were needed (Bauer, Schmitt et al. 2010). If anything, hand dermatitis in nurses is likely to become an even more important problem in the future. Hand hygiene measures will continue to be rigorously enforced in NHS sites. At the same time, retention of trained nurses in the workforce is likely to become increasingly important as it becomes necessary for people to work to older ages. Given the current economic climate, it is vital that new interventions implemented in the NHS be both clinically and cost-effective.

Our research will provide new evidence on a simple, practical intervention that will be deliverable throughout the NHS if found to be beneficial and cost-effective. Because this application responds to a commissioning brief, it is by definition an identified NHS need. Our task is to add science to the needs-led nature of the work by assembling a multidisciplinary team to deliver a high quality and definitive study to address the expressed need. This is fully consistent with the "needs-led, science added" mission of the HTA Programme

### **4.0 Feasibility study**

Prior to the commencement of the main trial, we undertook a feasibility study in Swansea (Wales) between February 2014-May 2014. The aims of the feasibility study were to assess the process, response rates and data collection tools to be used in the main study.

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### *Method*

Study procedures were followed as for the first stages of the main study at an intervention plus site. As in the main study, all student nurses who were due to start their first clinical placement, and who had a history of atopic disease or hand dermatitis (as indicated on the responses provided on a standard health questionnaire) were identified by the OH department in the course of their routine OH assessment and invited to take part. In addition, all full-time ICU nurses (those working 30 hours or more per week) on the ICU unit at the local health board were invited to participate. Those who agreed to participate were asked to complete Questionnaire A (with modifications for ICU nurses as in the main study), and their hands/wrists were photographed and swabbed using the proposed methodology for the main study.

Once the student nurses started clinical work, they were offered the written leaflet "Dermatitis: Occupational aspects of management. Evidence-based guidance for employees" and a paper version of the BCP. They were asked to develop implementation plans and were provided with personal supplies of emollients for use during the study period.) Once ICU nurses were recruited to the study, optimal equipment for hand cleansing and drying was placed on their ward, along with dispensers of moisturising cream. The written leaflet and paper version of the BCP was then offered to all ICU staff of the ward concerned (not only those individuals who have consented to take part in the study), and the uptake documented. Two weeks after the paper version of the BCP was offered the participants were asked to complete Questionnaire B about beliefs regarding prevention of dermatitis and participation in, and views on the BCP.

At the end of the study period, a sample of participants recruited to the study were invited to take part in an in-depth telephone interview designed to seek qualitative feedback on the acceptability and user-friendliness of the methods of data collection and the BCP. The lead OH clinician from the trust was also asked for feedback on the ease of implementation of the study protocol and data collection tools and study protocols.

### *Results*

Thirty two student nurses were identified as eligible for the study, 22 (69%) of whom were recruited into the study. 22(100%) of those recruited returned a completed questionnaire A and 10/22 (45%) returned a completed questionnaire B. Two (20%) of those who returned questionnaire B did not participate in the BCP. One hundred and forty-eight ICU nurses were identified as eligible for the study (including those not on shift). Twenty six eligible ICU nurses were on shift on the day of recruitment and all 26 (100%) were recruited into the study. 22 (77%) of those recruited returned a completed questionnaire A and 13/22 (60%) returned a completed questionnaire B. One (8%) of those who returned questionnaire B did not participate in the BCP. The baseline prevalence of hand dermatitis as diagnosed by the dermatologists was: 5/21 (23.8%) in student nurses (one had missing data) and 10/26 (38.5%) in ICU nurses. The photographic method for assessing the presence and severity of hand dermatitis was easy to implement by the fieldworker and the dermatologists. Without prior agreement of rules of diagnosing dermatitis between the dermatologist, the between observer agreement in the assessment of photographs was 0.5%. One dermatologist tended to diagnose erythema in isolation as evidence of dermatitis and the only diagnosed dermatitis when erythema was present in association with dryness of the skin. There was poor correlation between the participants' self-assessment of the presence of hand dermatitis versus the assessment by the fieldworker and the dermatologists. All participants agreed to have their hands swabbed, but only one swab (from a student nurse) was positive for a mild growth of *Streptococcus* Lancefield group A, the other swabs were negative for the organisms looked for. The paper version of the BCP was piloted was acceptable in format and appeared to be clearly understood by the study participants. Where necessary, amendments were made to address any problems that come to light from the pilot exercise. None of the study participants agreed to be interviewed after the feasibility study, but the fieldworker was interviewed by the trial manager and gave invaluable feedback on the practicalities of running the study at a grass root level.

### *Changes to the main study protocol as a result of the feasibility study*

The feasibility study provided an invaluable opportunity to test the study protocol / procedures, and to identify and address issues that were likely to arise in the main trial. As a consequence, minor amendments were made to the processes and procedures study protocol to enhance trial procedures and we are confident these amendments will contribute to overall success in the main trial.

Since there was poor agreement in the diagnosis of dermatitis between the fieldworkers, the study participants and the dermatologists, we have removed the requirement for field workers and participants to assess whether hand dermatitis is present. We will solely use the dermatologists' assessment. As a consequence all participants hands will be photographed at baseline (when questionnaire A is administered) and 12-15 months after the BCP is delivered in intervention plus sites (and at an equivalent time at intervention light sites). The dermatologist have agreed a set of rules by which they will diagnose hand dermatitis from the photographs and will assess a further 100 hand photographs to ensure that they achieve a good agreement between themselves (kappa >0.6). The swabbing of the participants' hands yielded little useful information. The Trial Steering Committee recommended that we do not swab hands in the main study. This recommendation was upheld by

NIHR so the requirement to swab hands has been removed from the main trial. The prevalence of dermatitis in the ICU and student nurses in the feasibility study allowed us to refine our power calculations for the main study.

## **5.0 Aims and objectives**

- 1) We will test the hypothesis that a bespoke, web-based behavioural change intervention to improve hand care, coupled with provision of hand moisturisers, can produce a clinically useful reduction in the prevalence of objectively assessed hand dermatitis after one year, when compared to standard care, in at-risk nurses working in the National Health Service (NHS).
- 2) Secondary aims will be to assess impacts on: participants' beliefs and behaviour regarding hand care (as a measure of adherence); days off sick over a one-year follow-up period and the use of hand moisturisers.
- 3) In addition, we will assess the cost-effectiveness of the intervention compared with normal care.

### *Concise statement of proposed research:*

We will conduct a cluster randomised controlled trial of an intervention to improve hand care, at 35 sites, (12 NHS acute hospital trusts / health boards which provide OH care to both student and ICU nurses, 18 NHS Trusts which provide OH care to ICU nurses and 5 University OH departments which provide OH care to student nurses). We will, focus on two groups of staff: (i) student nurses who are about to start their first clinical placements, and who are at increased risk of hand dermatitis because of a past history of atopic disease or hand eczema; and (ii) nurses working in ICUs, who are at increased risk of hand dermatitis because of the nature of their work

## **6.0 Research plan/ method**

### ***6.1 Design and theoretical/conceptual framework:***

The study will be a cluster RCT, based on sites as the unit of randomisation. Sites will be randomly selected to be an intervention light site (Sites A) or intervention plus site (Sites B). Study group one will be student nurses who are about to start their first clinical placements, and who are at increased risk of hand dermatitis because of a past history of atopic disease or hand eczema. Study group two will be nurses working in ICUs who are at increased risk of hand dermatitis because of the nature of their work.

#### *Intervention plus*

The intervention plus in both staff groups will centre on a bespoke on-line behavioural change package (BCP) which will include advice: on when and when not to use gloves; on when to use antibacterial hand rubs; on when to use moisturising cream; and to contact OH early if hand dermatitis occurs.

The BCP will be developed by members of the study team with expertise in dermatology (HW, JE), occupational medicine (IM, JS), nursing (TL), and health psychology (AW). Care will be taken to ensure compatibility with current guidance on infection control (Coia, Duckworth et al. 2006, WHO 2009). We will emphasise WHO recommendations that hands should only be washed with soap and water if visibly soiled. At all other times, hands should be cleansed with antibacterial hand gels (WHO 2009). Recommendations on glove use will be in line with recent RCN guidelines (Royal College of Nursing 2012).

To maximise the probability of participants acting on their intentions, they will be asked to form implementation intentions for performing each of the behaviours in their workplace. A record of his or her implementation intentions will be generated by the online BCP programme and e-mailed to each participant. Participants will be given the opportunity to revise their implementation intentions when first formed, and then will be e-mailed a month later, and reminded of their implementation intentions. In the event of a participant being unable to access the on-line BCP, participants will be posted a paper-based magazine version of the BCP. The magazine will reflect the information provided on the online BCP. Participants will be asked to read through the material provided and write down their action plans in the spaces provided. Participants will be asked to keep the paper-based BCP in a convenient place so they can refer back to it as required. .

The BCP will be supported by provision of facilities to encourage adherence. These will include personal supplies of moisturising cream for at-risk student nurses (study group 1), and provision of a) optimal equipment for cleaning hands and b) moisturising cream dispensers on intensive care wards (study group 2).

The package will be actively reinforced over the course of the study by consistent messages on skin care from the local OH and control of infection teams, and from local line management. Research has shown that senior role models have important effects on more junior healthcare workers' hand hygiene behaviours (Sax, Uckay et al. 2007, Whitby, McLaws et al. 2006) , and it seems reasonable to assume that this influence will extend to behaviours preventing dermatitis. To facilitate this, we

will, at the time of implementation of intervention plus, engage in a dialogue with local OH staff and line managers at intervention sites about the nature and purpose of the study and will provide them with information on the advice which will be given in the BCP, to ensure that they promote consistent messages on skin care. The SCIN research team will also write to each of the NHS sites where student nurses go on clinical placement but where the NHS site is not a participating study site to ensure they are informed of the study.

We propose to offer the BCP online to allow nurses to access it at a time convenient to their schedules, to permit standardisation of the delivery of key information across all intervention plus sites, and to reduce the potential burden of delivering the intervention on OH staff. Moreover, if the BCP is found to be effective in this trial, it will be simple to scale up access to the website in order to deliver the BCP across the country.

#### *Comparator (intervention light)*

Nurses at intervention light sites will be managed according to what would currently be regarded as best practice, with provision of an advice leaflet about optimal hand care “Dermatitis: Occupational aspects of management. Evidence-based guidance for employees” (also provided to the intervention plus group) and encouragement to contact their OH department early if hand dermatitis occurs. However, they will not receive the BCP or active reinforcement of its messages. Nor will they routinely be offered supplies of moisturising cream over and above what is already standard practice in their site.

#### *Comments on design*

As we are proposing a RCT design we have followed, as closely as possible, the most recent Consolidated Standards of Reporting Trials (CONSORT) updated guidelines for non-pharmacological interventions (Boutron, Moher et al. 2008). Randomisation by site is an appropriate design to decrease the risk of “contamination”, i.e. decrease the chance that controls would become aware of the messages, and adopt some of the behaviours, being promoted in the intervention. Such contamination may cause the benefits of an intervention to be underestimated. Our proposed study complies with the fundamental ethical principle of a RCT in that there is genuine uncertainty regarding the effectiveness of the BCP supplemented by ready access to optimal hand-care, as this intervention has not previously been tested in RCTs (equipoise).

### **6.2 Sampling:**

We identified all NHS sites in the UK, which train nurses, have an in-house occupational health (OH) service and have at least one ICU. We first wrote to the lead occupational physician in each eligible site in December 2011, asking their willingness, in principle, to collaborate in a trial; and we wrote again in May 2012 and January 2014 asking them to confirm their willingness to collaborate. We also invited additional sites to sign up to the study via national occupational health newsletters. In order to avoid the risk of student nurses moving placements from an intervention to a control sites (or vice versa) during the study period, we selected one site in each city or town to be invited to participate in the study. The exceptions were London and Manchester. In London, three sites were identified in which student nurses did not move to neighbouring sites during their training. In Manchester, we identified sites where students at three local universities undertake their clinical placements during their first year nursing training and ensured these sites were clustered appropriately to prevent cross contamination of the study.

A list of participating sites (OH departments) for the main study was finalised on 17 July 2015. A summary of the number of participating sites is provided below:

- 12 sites recruiting both ICU nurses and student nurses (NHS trusts/health boards)
- 18 sites recruiting ICU nurses only (NHS trusts/health boards)
- 5 sites recruiting student nurses only (University-based OH departments)

#### *Study group 1 student nurses*

All student nurses must attend for an OH screening prior to commencing their clinical work. At participating sites, with the permission of the universities, all student nurses in a single year group, excluding mental health nursing students, who are due to start their first clinical placement, will be sent a participant information sheet (see Participant Information Sheet: Student nurses) by their universities or their OH department prior to or at the time of their mandatory OH pre-clinical placement screening appointment. Those nurses who have a history of atopic disease or hand eczema will be identified either retrospectively or prospectively by the OH Department in the course of their routine OH assessment/hepatitis B immunisation. Health information provided by student nurses on the generic occupational health pre-placement health screening questionnaire will be used as a screening tool to identify potentially eligible participants. An OH clinician will explain to them that because of their constitution, they are at increased risk of hand dermatitis and therefore need to take special care of their hands. Those student nurses who meet the inclusion criteria will then be invited to participate in the study. The fieldworker in each site will take the consent from (see: Consent Form for Research Study) the nurses and the lead study OH practitioner in each site will be available to answer any questions as will the trial manager. The Consent Form

for Research Study will also request participants provide a preferred email address and telephone number so that student nurses in the intervention plus sites can be sent a link to the online BCP and in both intervention groups follow up reminders can be made requesting non-responders complete and return the study questionnaires. Email reminders will also contain a positive reinforcement message to encourage ongoing participation in the study. One copy of the signed consent form will be filed in the nurse's OH notes, one copy will be sent to the trial manager and one copy will be given to the nurse participant. Participants will be provided with an Information Sheet to give to their GP (see: GP Information Sheet).

As there is a theoretical risk that sites randomised to one arm may include a higher proportion of volunteers than those in the other arm, the recruitment process will be carefully documented. The total number of eligible nurses will be recorded, as will the number who consent to participate, together with the number who consent to participate but do not. We will also record the number of participants who drop out of the study, with the date of drop out).

#### *Study group 2 intensive care nurses*

The investigators, trial manager and lead OH clinician from each site will identify one or more ICUs at each participating site. A local OH clinician or senior ICU nurse will explain to all nurses working on the selected ICUs that they are at increased risk of hand dermatitis because of frequent hand-washing with cleansers and water. They will also be told that a study is being carried out to help optimise management of nurses who are higher risk. Only full-time ICU nurses (those working 30 hours per week) working in ICU in the selected site will be provided with a participant information sheet (see: Participant Information Sheet for ICU nurses) and they will be given up to a week to decide if they wish to participate in the study. The site fieldworker will invite the nurses to take part in the study. Consent (study consent form) will be taken by the fieldworker who will be available to answer any queries regarding the study as will the trial manager. One copy of the signed consent form will be filed in the nurse's OH notes, one copy will be sent to the trial manager and one copy will be given to the nurse participant. The Consent Form for Research Study will also request participants provide a preferred email address so they can be sent a link to the online BCP (in the intervention plus sites) and so follow up reminders can be made requesting non-responders complete and return the study questionnaires. Email reminders will also contain a positive reinforcement message to encourage ongoing participation in the study.

Participants will be provided with an information sheet to give to their GP (GP Information Sheet). We will, where possible, collect baseline data via Questionnaire A (ICU nurses) on those who consent to participate prior to unblinding the SCIN team or the Fieldworker to the randomisation.

Additional descriptive information will be collected in relation to the number of full-time and part-time nurses at each sites, the proportion of who meet the study inclusion criteria, the proportion who agree to participate and those who do not. (see: Site profile: Total number of student/ ICU nurses at this site)

The study will be presented to both study groups as research to assess the causes, consequences and ways of preventing hand dermatitis in nurses who are at increased risk, either because of a personal history of atopy or eczema, or because of the type of work that they do. However, to minimise the chance of bias, they will not be told that they are in an intervention plus or intervention light group.

Flowcharts will be used to support the study protocol and these will provide clear step-by-step instructional and procedural guidance to field workers on each of the research activities (including specific time-points) that require completion during the study period. They will cover both student nurse and ICU nurse cohorts and will reflect the intervention light and intervention plus arms of the study.

#### **6.3 Randomisation:**

The trial methodologist (DC) and statistician (GN) will develop a formal strategy (protocol) for randomisation, based on the final list of participating sites, and King's Clinical Trial's Unit will conduct the randomisation procedure.

If possible, before randomisation, the field worker at each participating site will provide information about current arrangements to minimise the occurrence of hand dermatitis in nurses and the procedure to manage it when it occurs. Among other things, this will cover: general training re dermatitis; guidance on when and when not to use gloves; guidance on washing and drying hands, and on use of hand rubs; advice on use of moisturising creams; and provision of moisturising creams for staff (see: Site Survey of Current Policy, Practice and Training worksheet). If there are major differences in practice between sites, we will consider stratification by current practice (in broad groups) before sites are randomised. Site will be stratified to ensure similar sample sizes exist in both intervention light and intervention plus arms. This will address issues where we anticipate low recruitment numbers at specific sites.



As described above, in order to ensure that the nurses are not influenced by prior knowledge of treatment allocation, we will ensure that only CTU will know if sites have been randomised to the intervention light or intervention plus arm of the study at the time that study participants are recruited and complete questionnaire A. However, for practical reasons, such blinding may not be possible for all participants.

For the purpose of the intention to treat analysis, the date of entry into the study for each of the participants will be date when they sign the Consent Form for Research Study. Although student nurses can only contribute useful information once they start clinical work, in practice very few fail to start their clinical work once they commence their nursing studies.

Study team members will be informed of the outcome of the randomisation via email, where possible, this will be after nurses have been recruited. Study team members will be informed of the randomisation in a blinded or unblinded manner, depending on their role in the trial. The trial statistician (GN), methodologist (DC), infection control expert (BC), dermatologists (HW, JE) will remain blinded to treatment allocation until after the primary analysis.

#### **6.4 Sample size:**

The primary endpoints are specified in section 6.7 on data analysis. Field workers will be encouraged to recruit as many eligible student nurses and ICU nurses as possible, with the aim of recruiting at least 40 student nurses and 40 nurses from the ICUs at each site.

To give an indication of power, we assumed that at the end of follow-up the expected prevalence rates overall at the intervention light sites would be 24% in both student and ICU nurses, that the intraclass correlation coefficient (ICC) is 0.05 (this corresponds to a variance inflation factor of 2.05 for student and 2.8 for ICU nurses), and that 20% of participants will be lost to follow-up. With a 5% level of statistical significance (two sided), we would have approximately 83% power to detect a reduction in prevalence of dermatitis at follow-up in the intervention plus sites to 10% in student nurses and 91% power to detect a reduction in prevalence to 10% at follow-up in ICU nurses. For final prevalence rates of 12%, the powers would be 68% for student and 78% for ICU nurses, while for final prevalence rates of 14%, the corresponding powers would be 51% and 61% respectively. The power will be higher if ICC is lower than 0.05. (These calculations were carried out using the `-clustersampsi-` command in Stata v12.1 for difference in proportions.)

#### **6.5 Setting:**

OH departments (NHS and university-based) in the United Kingdom (excluding the pilot site in Wales)

#### **6.6 Data collection:**

Local field workers will make use of individual 'study packs' when recruiting participants to the study. Study packs will contain each of the research documents (e.g. data collection worksheets, consent forms, Questionnaire A, business reply envelope etc) that require completion during the study period (Questionnaire B will not be included in these pack since they will be posted directly to participants by the SCIN research team based in London). Questionnaire C will be posted to field workers in participating sites two months before they are due to be given to study participants. A matching pre-assigned participant identification number (PIN) will be recorded on all research documents contained in each pack and these will be numbered sequentially to reflect the order in which they are to be completed. A unique PIN will be allocated to each participant as they are recruited to the study. The local field workers will then record the PIN, participant initials and date of birth on a separate Participant Registration Log sheet as participants are recruited to the study. Each participating site will be assigned a unique Site Code for use during the study. The site code will match to first two digits of the PIN.

During the recruitment phase, field workers will reinforce the importance that participants are able to fully commit to the study, particular with respect to the completion of each of the study questionnaires.

#### **Study group 1 student nurses**

Student nurses who agree to take part, will be asked to complete a consent form and a self-administered baseline questionnaire (see: Questionnaire A: Student Nurses), covering: contact details (which for security reasons will be kept separate from the rest of the questionnaire); demographic information; history of atopic disease and allergies; activities outside work which predispose to hand dermatitis; beliefs and plans regarding dermatitis prevention behaviours; the Euroqual-5D (EQ-5D) health-related quality of life questionnaire (The EuroQol Group 1990) and history of hand dermatitis ever, in the past 12 months, and currently. Student nurses will be asked to place the completed questionnaire into a sealed business reply envelope and return this to the field worker. This will then be forwarded to the SCIN research team in London. If the student nurse wishes they may send the completed questionnaire directly back to the SCIN team in London.

After Questionnaire A has been completed, all student nurses will have their hands and wrists photographed (as per SOP: Photography). At the follow up time-point (T=12-15 months), participants will be provided with an opportunity to send the SCIN research team 'selfie' photographs of their hands/wrists in circumstances where the local field worker is unable to make personal contact with them. Subject to acceptable results from a sensitivity analysis, collection of 'selfie' photographs

will enable the research team to report on the primary outcome measure. At the time of the photograph, student nurses will be asked to complete a form evaluating whether or not they consider that they have dermatitis and the extent to which it interferes with work and hobbies (dermatitis self assessment form). The nurse will be asked to place the completed form in a sealed envelope and give it back to the fieldworker who will collect the completed self assessment forms and send them to the SCIN research team in London. Where active dermatitis is present, the local OH departmental procedure for the management of hand dermatitis will be followed. Separate consent will be obtained from the participating nurses each time their hands are photographed (see: Consent Form for Photographs). Field workers will give participants oral information about hand dermatitis and provide them with the Dermatitis: Occupational Aspects of Management written leaflet. Participants will also be told that they may be sent an online BCP which they should undertake in the week before starting their first clinical attachment, and to which they will be sent a link (by email) two weeks before the attachment begins. At that time, they will also be sent (by post) a personal tube of moisturising cream with guidance on how to request further supplies if needed. Participants will be required to log onto the online BCP programme and register as a first-time user.

All participants in, both the intervention plus and intervention light sites, will be encouraged (orally, through the written advice leaflet, and by email reminders at 4 and 8 months) to attend their OH Department at an early stage should they develop hand dermatitis.

One week after starting their first clinical attachment, all participants will be asked to complete a further short self-administered questionnaire (see: Questionnaire B: Student Nurses), covering beliefs and plans regarding dermatitis prevention behaviours. At intervention plus sites, it will also ask about participation in, and views on, the BCP. Questionnaire B will be sent by post to participants by the SCIN research team. A business reply envelope will also be provided so completed questionnaires can be returned.

In order to account for seasonal variations in the prevalence of dermatitis, the final study data collection tools will be administered 12-months after questionnaire A. All participants will be asked to answer a third self-administered questionnaire, (Questionnaire C: Student Nurses) and to have their hands photographed. At the time of the photograph, student nurses will be asked to complete a form evaluating whether or not they consider that they have dermatitis and the extent to which it interferes with work and hobbies (dermatitis self assessment form). The nurse will be asked to place the completed form in a sealed envelope and give it back to the fieldworker who will collect the completed self assessment forms and send them to the SCIN research team in London. Questionnaire C will be given out by the local fieldworkers. Questionnaire C will cover: clinical attachments undertaken in the past year; hours worked per week over the past year; beliefs and plans regarding dermatitis prevention behaviours; participation in, and views about, the BCP (only at intervention plus sites); activities outside work which predispose to hand dermatitis; recent practices regarding use of gloves; recent practices regarding hand cleansing ;recent use of moisturising creams; history of hand dermatitis in the past 12 months (including its investigation and treatment, and any consequent loss of time from work or restriction of duties); and the EQ-5D questionnaire. Student nurses will be asked to place the completed questionnaire C into a sealed business reply envelope and return this to the field worker. This will then be forwarded to the SCIN research team in London. If the student nurse wishes they may send the completed questionnaire directly back to the SCIN team in London.

Information on the number and date of attendance at OH with symptoms of hand/wrist dermatitis and requests for extra provisions of emollients will also be recorded (see: Recording Provision of Extra Emollients).

#### *Study group 2 intensive care nurses*

At both intervention plus and intervention light sites, all nurses who work on the ICUs selected for study will be given the participant information sheet (see: Participant Information Sheet: ICU nurses) about the study. Those who agree to participate will be asked to complete a Consent Form for Research Study and self-administered questionnaire (see: Questionnaire A: ICU Nurses). This will be similar to Questionnaire A: Student Nurses, but will also include items on current occupation; recent practices regarding use of gloves; recent practices regarding hand cleansing; recent use of moisturising creams; and any sickness absence or modification of duties during the past 12 months because of hand dermatitis. ICU nurses will be asked to place the completed questionnaire into a sealed business reply envelope and return this to the OH clinician (field worker). This will then be forwarded to the SCIN research team in London. If the nurse wishes they may send the completed questionnaire directly back to the SCIN team in London.

All ICU nurses will have their hands and wrists photographed (as per SOP: Photography). At the follow up time-point (T=12- 15 months), participants will be provided with an opportunity to send the SCIN research team 'selfie' photographs of their hands/wrists in circumstances where the local field worker is unable to make personal contact with them. Subject to acceptable results from a sensitivity analysis, collection of 'selfie' photographs will enable the research team to report on the primary outcome measure. At the time of the photograph ICU nurses will be asked to complete a form evaluating whether

or not they consider that they have dermatitis and the extent to which it interferes with work and hobbies (dermatitis self assessment form).. The nurse will be asked to place the completed form in a sealed envelope and give it back to the fieldworker who will collect the completed self assessment forms and send them to the SCIN research team in London. At the time of taking hand/wrist photographs study participants who are found to have active hand dermatitis will be given advice in accordance with local OH departmental procedure for the management of hand dermatitis. Separate consent will be obtained from the participating nurses each time their hands photographed (photograph consent form).

At intervention plus sites, once participants have been recruited, field workers (OH clinicians) will promote the importance of optimisation of equipment for hand cleansing, and dispensation of moisturising cream. The written leaflet occupational aspects of management will be available to all staff on the ward (not only those individuals who have consented to take part in the study). An email will also be sent via the Lead ICU nurses to all staff on the ward with a link to the BCP, and the uptake documented.

At intervention light sites, participants will be given the written leaflet about prevention of hand dermatitis (see: Dermatitis-Occupational Aspects of Management). Two weeks after the BCP is offered (or at a similar interval after recruitment in the intervention light sites), participants will be asked to complete Questionnaire B: ICU Nurses about beliefs regarding prevention of dermatitis and (at intervention plus sites) participation in, and views on the BCP. Questionnaire B will be sent out in the post to participants by the SCIN research team along with a business reply envelope. All participants at, both the intervention plus and intervention light sites will be encouraged (orally, through the written advice leaflet and by email reminders sent out by the SCIN research team at 4 and 8 months) to attend the OH Department at an early stage should they develop hand dermatitis. Email reminders will also contain a positive reinforcement message to encourage ongoing participation in the study. At the intervention sites, the email reminders will also reinforce the BCP.

In order to account for seasonal variations in the prevalence of dermatitis, the final study data collection tools will be administered 12-months after questionnaire A. All participants will be asked to have their hands/wrists photographed and to complete questionnaire C. At the time of the photograph ICU nurses will be asked to complete a form evaluating whether or not they consider that they have dermatitis and the extent to which it interferes with work and hobbies (dermatitis self assessment form).. The nurse will be asked to place the completed form in a sealed envelope and give it back to the fieldworker who will collect the completed self assessment forms and send them to the SCIN research team in London. Questionnaire C will be sent out in the post to field workers two months before the end of the study, by the SCIN research team. The field workers will give the ICU nurses questionnaire C at the time that they recall them to have their hands photographed. Fieldworkers will ask the participants to complete questionnaire C. The nurses will be asked to place the completed questionnaire into a sealed business reply envelope and return this to the field worker. This will then be forwarded to the SCIN research team in London. If the nurse wishes they may send the completed questionnaire directly back to the SCIN team in London. If it is not possible for a ICU nurse to complete the questionnaire at the time, then they will ask the study participants to return the completed questionnaire to the SCIN team directly (a business reply envelope will be provided).

Participants who decide to withdraw from the study for whatever reason will be requested complete a shortened version of Questionnaire C and will be invited to have follow-up hand/wrist photographs taken. The collection of this data will enable the researchers to further report on the study's primary objective measure i.e 'changes in the point prevalence of visible hand dermatitis from baseline'. Participants will be asked to complete a Consent Form for Photographs of Hand before this data is collected.

#### Study instruments and data collection tools

##### *Questionnaires*

We will use paper-based study questionnaires which will be identified by the unique participant information number (PIN). For security reasons, contact details will be kept separately. Their content is described above. Throughout the study, non-responders to any of the three study questionnaires will be sent an email reminder from the SCIN research team with a request that they complete and return the questionnaire to the SCIN team. If questionnaires remain outstanding, another copy of the paper questionnaire will be posted to participants' preferred postal address along with a business reply envelope. If questionnaires remain outstanding after another two weeks, participants will be sent up to two reminder text messages (or telephone message if they have left a land line number).

At the end of the study period, participants who have completed and returned all three study questionnaires will be entered into a prize draw with participants given a chance of winning one of the study cameras ( 26 cameras will be offered, this may increase to a maximum of 30 cameras if a surplus supply exists at the end of the study). Participants who have not completed and returned all three study questionnaires will not be eligible for entry to the prize draw. Information about the draw and

prizes has been provided on the Participant Information Sheets. The research team recognise there may be circumstances, albeit rare, where some participants may be reluctant to send in selfie photographs of their hands/wrists at the end of the trial, particularly if they're concerned that any potential signs of hand dermatitis may be reported by the research team to local management. Accordingly, these participants will be posted a letter of reassurance that information obtained will not be shared with local management along with a brief questionnaire and a request that they provide clarifying information in this regard.

#### *Ascertainment of hand dermatitis and description of the photographic method*

Participants with symptoms of hand dermatitis in the past three months will be identified through a screening question as outlined in the questionnaires "Have you ever had hand eczema or dermatitis?" and if so "Have you had hand eczema or dermatitis in the last 3 months" which has been developed from the Nordic Occupational Skin Questionnaire (Susitaival, Flyvholm et al. 2003) and which is currently being used in an intervention study to implement guidelines aimed at reducing hand eczema in healthcare workers in three teaching hospital in the Netherlands (van der Meer, Boot et al. 2011).

All participants will be invited to have their hands/wrists photographed (as per SOP: Photography). This will include the option of participants providing 'selfie' photographs of their hands/wrists at the follow up time-point (T=12-15 months). A separate protocol for selfies will be produced: the SOP Selfie 'The SOP Photography has been developed in consultation with a medical photographer and is consistent with the views required for the photographic assessment scale described by Coenraads (Coenraads, Van Der Walle et al. 2005). The SOP: Photography describes the process of obtaining repeatable standardised photography of the hand, to illustrate skin condition with respect to area affected and standard colour comparisons, the procedure for recording participant identification numbers (PINs) and date on each of the digital images that are taken, and the procedure for transferring images securely using recorded delivery to Guy's and St Thomas' NHS Foundation Trust. The following outlines the procedure that will be used for assessing the photographic images collected during the trial and has been approved by the Trial Steering Committee.

#### *Procedure for assessing photographic images collected during the trial:*

1. STEP 1 Photographic images (baseline and follow up) from each participating site will be sent to a trained dermatology research nurse (JL) as soon as the first site has completed the collection of follow up photographic images.
2. STEP 2: Dermatology nurse will formally review and assess all images for the presence (or absence) of hand/wrist dermatitis. A photographic scoring worksheet will be completed during this process. During this process, images will be stored one of the following electronic folders:
  - Folder 1: Images where there are 'clear' (*no signs of hand/wrist dermatitis*)
  - Folder 2: Images where the dermatology research nurse is '*not sure*' if there are signs of hand/wrist dermatitis
  - Folder 3: Images where there are *signs of hand/wrist dermatitis*
3. STEP 3: Photographic images stored in folder 2 and folder 3 will be sent to the SCIN trial dermatologists (HW and JE) for independent scoring. Using the Photographic Scoring worksheet, the dermatologists will assess and record the presence or absence of hand/wrist dermatitis according to the five grades described by Coenraads, Van Der Walle et al, 2005). That is, images will be assessed as "clear", "almost clear", "mild, moderate", "severe" and "very severe".
4. STEP 4: Completed Photographic Scoring worksheets will be returned to the SCIN research team for processing.
5. STEP 5: SCIN research team will compile a list of discordant cases. That is, cases where there was a disagreement in the presence or absence of hand/wrist dermatitis between the two dermatologists.
6. STEP 6: The dermatologists will meet to discuss discordant cases. If they are still unable to agree, the four images relating to the respective participants will be sent to a third dermatologist whose decision will be final.

#### SENSITIVITY ANALYSIS

To ensure the dermatology research nurse has undertaken a robust assessment of the photographic images and is able to confidently screen out positive and negative ("clear") cases, a subsample of 250 cases that are assessed as "clear" of hand/wrist dermatitis will be sent to the dermatologists for their independent assessment.

Our rationale for ascertaining any, and not only more severe hand dermatitis, is that even minimal hand dermatitis progresses to significant hand eczema in a cumulative way over time (Baumeister, Weistenhofer et al. 2009). However, we will also grade disease severity since severe hand dermatitis causes more distress and is associated with greater loss of time from work. We will use one method for classifying hand eczema severity: i.e. a simple categorization into five grades (clear, almost clear, mild, moderate, severe and very severe) using a validated severity scale developed by Coenraads et al (Coenraads, Van Der Walle et al. 2005). This scale has been widely used in other occupational hand eczema prevention studies (Skudlik, Dulon et al. 2006).

We have considered other methods for assessing hand dermatitis prevalence based on teledermatology and have rejected them because (i) the technology would add significantly to the cost of the trial in terms of equipment and training (ii) teledermatology is not routinely used in occupational health for hand dermatitis assessment thereby limiting study generalisability and (iii) research suggests that the severity of dermatitis can be over-estimated using such an approach (Baumeister, Weistenhofer et al. 2010).

A recent systematic review of 49 different methods for assessing hand dermatitis by Weistenhofer (Weistenhofer, Baumeister et al. 2010) identified just three as being adequate, with the OHSI probably the one best suited to studies of hand dermatitis that includes a lot of participants with mild disease. The scale has been used extensively, including as a photographic tool (Baumeister, Weistenhofer et al. 2010), it has been tested for reliability (Skudlik, Dulon et al. 2006), and sensitivity to change (Dulon, Pohrt et al. 2009) and it has also been used in a health care professional setting (Skudlik, Dulon et al. 2009). In addition to presenting the OHSI scores to aid comparability to other studies and to facilitate meta-analysis, we will also dichotomise the score into very severe (score greater than 7) and other severities as recommended by the scale developers (Dulon, Pohrt et al. 2009). Other more recent scales such as the HEROS rely on detailed physical examination, which is impractical in this cluster RCT (Weistenhofer, Baumeister et al. 2011).

### **6.7 Data Analysis:**

Outcomes will be assessed separately for the two study groups (student nurses and nurses in ICUs).

#### *Outcome measures*

For each study group, the principal outcome measure will be the difference between intervention plus and intervention light sites in the change in point prevalence of visible hand dermatitis from baseline to the end of follow-up. A prevalence measure has been chosen as: (i) hand eczema is usually chronic; (ii) prevalence provides a good measure of the burden of disease in healthcare workers; and (iii) it can be ascertained in a blinded way, thereby minimising information bias.

Secondary outcomes will be the difference between intervention and control sites in:

- The difference between intervention and control sites in the change in prevalence and severity of visible hand dermatitis from baseline to the end of follow-up (as ascertained by the dermatologists)
- Days lost from sickness absence and days of modified duties because of hand dermatitis per 100 days of nurse time during the 12-months of follow-up
- The change from baseline to after completion of the BCP, and to the end of the 12-month follow-up in beliefs about dermatitis prevention behaviours.
- The change from baseline to the end of follow-up in the reported frequency of: use of hand rubs for hand cleansing; hand-washing with water; and use of moisturising creams (for student nurses, who will not have started clinical attachments at the beginning of the study, this will reduce to differences between the intervention and control sites at the end of the follow-up)
- The change from baseline to the end of follow-up in quality of life score
- The use of moisturiser provided for the intervention (in terms of requests for further supplies by student nurses and orders for supplies of moisturisers by ICUs).

We will also document the reported participation in the behavioural change package, reasons given for not participating, and comments on its content.

#### *Method of analysis*

Differences in changes in the prevalence of the primary and secondary outcomes from baseline to follow-up between the two arms will be assessed by random-intercept multilevel models to account for possible clustering by site. For the primary outcome, the relative odds of having dermatitis at follow-up in the intervention plus group as compared to the intervention light group after adjusting for dermatitis at baseline will be estimated using random-intercept logistic regression model. If inadvertent potentially confounding changes occur at some sites during the course of the study, we will carry out sensitivity

analyses excluding the sites concerned. We will test whether differences between the intervention and control groups in dermatitis prevention behaviours are mediated by differences in beliefs and plans about the relevant behaviour.

### *Economic analysis*

In addition to analyses of clinical effectiveness, we will assess the cost-effectiveness of the interventions in the two staff groups from a healthcare and societal perspective. Healthcare costs will be calculated for the 12-month follow-up period and will be based on the number of contacts with clinical staff (occupational health, primary care staff, dermatologists, etc) as a result of hand dermatitis, combined with appropriate unit cost information (Curtis 2011) and the cost of supplying moisturising creams (with costs obtained from the BNF for prescribed formulations). The service use information will be collected using a short self-report schedule based on the Client Service Receipt Inventory (Beecham & KnappThornicroft 2001), versions of which have been used in at least 300 studies in the UK and internationally. These service costs will be added to the cost of the BCP itself, which will be based on development time and staff time accessing the package. Societal costs will be calculated by adding healthcare costs to the costs of lost production, based on days off work combined with wage rates. Cost comparisons between the groups will be made using bootstrapped regression models assuming that the cost data are skewed. Costs from both perspectives will be combined with the primary outcome measure in a cost-effectiveness analysis. If costs are reduced for one group and outcomes are better then it will be 'dominant'. If one group has higher costs and better outcomes then incremental cost-effectiveness ratios (ICERs) will be generated, defined as the difference in costs divided by the difference in outcomes. Using the primary outcome measure, the ICER will indicate the extra cost incurred for one extra participant to be free of visible hand dermatitis in either hand at 12-month follow-up. There will be uncertainty around the cost and effectiveness estimates and this will be addressed using cost-effectiveness planes generated through repeated resampling from the data set to generate 1000 cost-outcome combinations and plotting these. To inform health care spending decisions it is helpful to also combine costs with quality-adjusted life years (QALYs). The most widely used QALY measure in England is the EQ-5D, which has been recommended for dermatological interventions (Shikier, Willian et al. 2006). This measure will be used at baseline and follow-up and area under the curve methods used to produce QALYs. Similar analyses as those described above will be conducted to assess the relationship between costs and QALYs but we will also generate cost-effectiveness acceptability curves (CEACs) to show the probability that the intervention is cost-effective for different threshold values placed on a QALY (Fenwick, Byford 2005). NICE appears to use a threshold of £20,000-£30,000 and so the range used here will include these values. (CEACs can also be used for the primary outcome measure but there are no accepted threshold values for an individual being free of dermatitis. CEACs will still be produced but will be more exploratory; they will be used to identify threshold values where the likelihood of the intervention being cost-effective is 50%, 60%, 70%, 80% and 90%). While standard unit costs are being used for most services it will be necessary to calculate the intervention costs specifically for the study. This will be based on estimates of staff time spent developing the intervention and staff time spent accessing it. We will increase/decrease both of these aspects in sensitivity analyses by 10-50% to see the impact that these changes have on the probability that the intervention is cost-effective at the £20,000 and £30,000 QALY thresholds. Sensitivity analyses will also be conducted on the societal cost-effectiveness estimates by increasing/decreasing the cost of lost work time by 10-50% and assessing the impact on the CEACs.

If the intervention is shown to be cost-effective then we will make estimates of the number of nurses who might access the intervention were it to become recommended practice. This will in turn allow us to estimate the budget impact for the NHS and the benefits in terms of total QALYs gained. Uncertainty around these estimates will be investigated through the sensitivity analyses describe above.

### *Process evaluation*

We will collect data on and describe:

- a) Uptake of the intervention, in terms of
  - Proportion of eligible nurses who accessed the online BCP
- b) Acceptability of the intervention in terms of
  - Perceived interest, relevance to role and likelihood of recommending it to colleagues

## **7.0 Dissemination and projected outputs**

The major outputs of the study will be:

- 1) A clinical and cost-effectiveness evaluation of a complex intervention to prevent irritant hand dermatitis in nurses
- 2) An on-line BCP
- 3) A protocol and photographic method for evaluating the presence and severity of dermatitis in the workplace
- 4) If our study shows that the intervention is clinically and cost-effective, it can be rolled out across the NHS and other healthcare organisations. The intervention is designed to be generalisable and will be applicable to other healthcare workers at risk, in particular doctors and cleaners. The intervention may also be suitable for use in other

high-risk industries such as hairdressing. Whether or not the intervention is found to be clinically and cost-effective, our study will have produced a standardised protocol and photographic method for evaluating the presence and severity of dermatitis in the workplace. This could have utility in clinical settings across many workplaces, especially where workers and their doctors do not have ready access to a dermatological opinion – for example, in the offshore oil industry.

- 5) As well as addressing an important practical problem, it is envisaged that this study will act as a catalyst for development of a stronger OH research base nationally. Two recent reports for Government by Black (Black 2008) and Boorman (Boorman 2009) both highlighted the need to strengthen the research base in occupational health. To date, few OH studies have received funding from NIHR and few OH departments have had the opportunity to participate in CLRN portfolio studies. This study will enable OH departments to develop research expertise, which should in turn encourage them to become more research active. The proposal has been developed by a collaboration of NHS and academic staff, who come from different disciplines. Given the complex nature of many OH interventions, we hope that this study will act as an example of how complex OH interventions can be evaluated in a robust, scientific manner. The study will involve 35 NHS acute sites and it is envisaged that once this research network is established, we would be able to capitalise on the network and be in a good position to deliver future studies.

#### *Methods of dissemination*

- 1) A 'dissemination group' (DG) led by the chief investigator IM will lead on the dissemination. The DG will comprise of principal investigators JE (dermatology), TL (nursing), AJW (health psychologist), VP (trial manager), a member of the KCL Trials Unit plus WT (lay member) and KH (chair of the trial steering group). The DG will report to the trial steering group. IM has contacted the Guy's and St Thomas' NHS Foundation Trust intellectual property manager and they have in turn been in contact with the local academic health sector network coordinator who has confirmed that they would wish to be involved in the dissemination of the results and adoption of good practice. IM will contact the academic health sector network coordinator once we start disseminating the study findings.
- 2) The OH leads from each participating site will be invited to a meeting at the end of the project, to inform them of the results of the trial and will be asked to disseminate the results to the participants in their site and to the site's management board.
- 3) As well as overseeing the trial, we expect the trial steering group to advise on the optimal dissemination of the results to NHS staff and key decision makers within the NHS and the Department for Health.

The study findings will be submitted for:

- 1) Publication in peer-reviewed journals (including, if appropriate, the findings from the feasibility study)
- 2) Presentation at the Society of Occupational Medicine annual scientific meeting, and at conferences of the International Commission on Occupational Health (EPICOH and/or Healthcare Workers).
- 3) Publication in professional newsletters including, the health and work network newsletter (sent electronically to over 100 OH departments in NHS sites); British Association of Dermatologists newsletter and the Society of Occupational Medicine newsletter.
- 4) Consideration in the development of new clinical guidelines. Two national guidelines have recently been published on occupational dermatitis, 'Occupational aspects of the management of dermatitis' (NHS Plus, Royal College of Physicians, Faculty of Occupational Medicine. 2009) and 'occupational contact dermatitis' (Nicholson, Llewellyn 2010). Three of the principal investigators of this study (JS, IM, JE) were closely involved in the development of these guidelines. Neither publication addressed the prevention of irritant dermatitis in the workplace. The results of this study could contribute to the development of a short clinical guideline with recommendations for prevention of hand dermatitis in healthcare workers.
- 5) The study report will be made available to all study participants.

### **8.0 Plan of investigation and timetable**

#### Phase 1

*June- August 2013* – Obtain ethical and governance approval for the study.

*Output:* ethical and governance approvals obtained

*September - December 2013-* Recruitment of research staff; development of questionnaires, various protocols (including hand photography, active dermatitis protocol and bacterial culture) and development of BCP. Local approvals and agreements with Welsh health board and associated hospital recruited to feasibility study.

*Output:* study data collection tools ready for use in feasibility study. Research staff recruited

*January -May 2014*

Undertake feasibility study

Obtain local approvals and agreements with NHS Sites recruited to main study

*June- August 2014-* Analysis of feasibility study.

Progression criteria: at July 2014 – no irremediable problems with BCP or methods of outcome assessment, and adequate projected study power as agreed with the trial steering committee and funder

Refinement of BCP and study collection tools in light of feedback from feasibility study.

Output: decision on progression to main study.

*July 2014* training workshop in London and Leeds for OH leads of each participating site (led by Dr Ira Madan and Dr Julia Smedley)

All local agreements with participating sites in place and the BCP and study collection tools refined for fit for purpose

Apart from sign off from ethical committee for substantive change to protocol, this timetable has been met.

## Phase 2

*September 2014- January 2016* Recruitment of participants; baseline data collection; delivery of interventions

Write up feasibility study for submission to peer reviewed journal

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*September 2015- April 2017* follow-up data collection and data cleaning

## Phase 3

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*May 2017- November 2017* analysis of data and writing up

Output: Final report for funders and papers for submission to peer-review journals and abstracts for submission to conferences. Conference for OH leads from participating sites to disseminate results.

## **9.0 Project management**

The study will be supervised in accordance with Medical Research Council guidelines on developing and evaluating complex interventions (MRC Guidelines 2000) and the Medical Research Council guidelines for good practice for clinical trials 1998 (MRC Guidelines 2006).

*The project will be overseen by three separate groups*

- 1) The operational management group will consist of the Mr Vaughan Parsons, , Ms Caroline Murphy, Dr Alison Wright, Dr Ira Madan, Mrs Barbara Smiley. Other members of the research team will be co-opted into individual meetings as required. The operational management will meet face-to-face monthly for the first six months of the project and 4-6 weekly thereafter throughout the project duration to ensure the smooth day-to-day running of the project, adherence to the project timetable and adherence to the project budget. The group will also review recruitment to the main trial.
- 2) The trial management group will be responsible for overseeing the methodology of the trial, ensuring that the trial complies with ethical guidance, runs to budget and project timelines. The group will consist of Dr Ira Madan, Professor Hywel Williams, Professor David Coggon, Professor Barry Cookson, Professor Paul McCrone, Ms Caroline Murphy and Mr Vaughan Parsons. The project administrator will be in attendance. The trial management



group will meet annually in London, and ad hoc as required, by teleconference during the project period. The first meeting will be before the commencement of the feasibility study and at least annually thereafter to coincide with the key project milestones.

The research team have held four highly successful teleconferences during the development of the outline and full project proposal and we are confident that ad hoc meetings of the trial management group can be held by teleconference.

- 3) The trial steering committee (TSC) will provide overall supervision of the trial and will ensure that the requirements of the standards required in and the Medical Research Council guidelines for good practice for clinical trials 1988 (ref) are met. These come under the headings: Patient safety; trial progress; adherence to study protocol; consideration of new information; dissemination and implementation of results; complaints procedure and compensation for participants. As the trial will not be monitored by a data monitoring and ethics committee (as agreed with NIHR HTA, May 2013) a major role of the TSC will be advise on the implications of protocol changes, in particular the need to add more centres as either some drop out or insufficient nurses sign up to take part.

The TSC will meet face-to-face in London four times during the period of the study. The first face-to-face meeting will take place in July 2014 after the feasibility study and prior to the commencement of the main trial.

The following members of the TSC have been appointed by HTA: Dr Kit Harling CBE, a recent former senior OH advisor to the Department of Health (Independent Chair) Professor Peter White (Psychiatrist and trialist), Wendy Taylor (patient representative), Dr Ira Madan (chief investigator), Dr Lesley Rushton (co-investigator), Dr Gopal Roa (Infection control specialist), Dr Graham Johnston (dermatologist). Dr Isabel Reading (statistician and observer)

#### **10.0 Approval by ethics committee**

Approval for the study will be obtained in advance from management and staff representatives at the participating sites. Informed consent will be sought from all individual nurse participants before entry to the study, and separate individual consent will be obtained for hand photography. Individual consent will not be sought for interventions at a ward level (e.g. provision of optimal facilities for hand cleansing and glove use) since these are considered good practice, and individual consent would not be practical.

Although nurses at intervention light sites will not receive the BCP (which may or may not be effective), they will benefit from advice on skin care and active management of any hand dermatitis that occurs during the study, which in no case will be inferior, and some cases will be superior to the management which they would receive if they were not in the trial. In addition they will receive a handcare leaflet at the beginning of the trial. Moreover, if the intervention plus proves cost-effective, it can be extended to the intervention light sites.

Data collection will be organised such that names and contact details of individuals who take part in the study are held separately from other personal information, which will be identified only by a serial number. Identifiable information about nurses who are eligible for study, but decline to participate, will be restricted to members of their OH service (who already have access to their OH records). No information will be published in a form that could lead to the identification of individuals.

The NHS Research Ethics Committees has given ethical approval for the study.

#### **11.0 Patient and public involvement**

The patient involvement in this study differs from other studies in that the 'patients' are NHS nurses.

We have involved a patient representative, Wendy Taylor to

- 1) ensure that the proposed interventions and data collection tools are acceptable
- 2) seek her expertise on the planning and management of the trial
- 3) seek her expertise on the optimum dissemination of the trial results to ensure that they reach the target audience.

Wendy Taylor is a midwife with a history of hand dermatitis acquired during her nurse training. She commented on the draft proposal, is a member of the Trial Steering Committee and attended the one of the training workshops for fieldworkers.

### **13.0 Conclusion**

In conclusion, moisturisers are justifiable as part of our complex intervention as there is reasonable evidence that (as part of a complex intervention) they will improve skin condition. However, this study will add usefully to the limited evidence base for the use of moisturisers in practice in workplace environments.

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