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[Intervention Protocol]

Hygiene and emollient interventions for maintaining skin integrity in older people in hospital and residential care settings

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of hygiene and emollient interventions for maintaining skin integrity in older people in hospital and residential care settings.

BACKGROUND

Description of the condition

Globally, the population is ageing, and this is a particular issue in the western world (DESA 2013). The number of older people living in care settings and occupying hospital inpatient beds is rapidly rising (CDCP 2013a; CDCP 2013b; DH 2006; PSSRU 2011).

As with all organs of the body, age affects the skin, which inevitably becomes more vulnerable to damage (APGS 2000; Fore 2006). The skin, as the largest organ system in the human body, represents the first point of contact for virtually all objects, organisms, and other factors that interact with the body. Skin integrity is essential in many ways for maintaining the body, such as temperature regulation and protection of deeper tissues from ultraviolet radiation and pathogenic organisms.

The term 'skin integrity' refers to the skin being a sound and complete structure in unimpaired condition. Conversely, impaired

skin integrity is defined as an “altered epidermis and/or dermis...destruction of skin layers (dermis), and disruption of skin surface (epidermis)” (NANDA 2013).

As skin ages, it undergoes numerous degenerative changes, both intrinsic and extrinsic (Farage 2007; Ronda 2002). Intrinsic skin ageing is due to ‘programmed’ true biological changes (Lawton 2007). Please see Table 1 for a list of intrinsic skin changes and their effects on the skin. Additional factors, such as damage as a result of the skin’s exposure to the environment (Coddell 2011), including ultraviolet light, cause extrinsic ageing. Other influences on older people’s skin health include frequent washing, particularly with harsh products; lack of hygiene (producing a build-up of potential pathogens and an increased risk of infection); trauma; reduced peripheral sensation; reduced mobility; incontinence; depression and dementia; poly-pharmacy (taking multiple medications); diabetes and vascular changes; and poor nutrition (Coddell 2011; Finch 2003). The cumulative effect of the ageing process is that the skin becomes a less effective barrier, risk of infection increases, and wound healing is delayed (Lawton 2007). These changes make the skin significantly more vulnerable to damage (Baranoski 2004).

It is generally agreed that xerosis (skin dryness), fissures (cracks), and pruritus (itching) are common in older people. However, these conditions often go untreated (Kirkup 2008). Whilst such conditions may be considered ‘minor’, they can have a significant impact on the individual and society. Xerosis brings with it an increased risk of other signs and symptoms including discomfort, itch, infection, skin lesions, and pressure ulcers (Cole 2004; Hunter 2003). Evidence about the prevalence of skin problems in older people is limited. Few epidemiologic surveys have been undertaken, and each has different methodology and populations (Fleischer 1996). A small number of studies have investigated the prevalence of skin problems in the ‘well’ older population (i.e., those not presenting for skin care related consultation). These studies are dated; however, there is also a dearth of up-to-date research. In an attempt to provide clinically relevant data about skin disease and skin care needs in older people, Beauregard 1987 examined the skin of 68 non-institutionalised volunteers aged 50 to 91 and questioned them. This revealed that 66% of the whole group reported skin problems, rising to 83% for octogenarians, and the most common disorder was pruritus (itch). Similarly, 204 people aged over 64 were questioned and examined; 70% reported pruritus in the week before the examination; 34% asserted that their pruritus could not be ignored; and 64% described a non-itching skin condition that bothered them (Fleischer 1996). It is estimated that xerosis affects 59% to 85% of older people (Beauregard 1987). Impairment in skin barrier function has the potential to cause significant morbidity (Farage 2007).

It is particularly important to make an additional effort to protect the skin of older people given the reduced elasticity of the skin; the increased risk of having chronic diseases that reduce the skin’s ability to repair damage, such as diabetes and cardiovascular diseases;

and the numerous psychosocial factors that come with increasing age and which increase the likelihood of skin breakdown.

Personal hygiene is one of many factors that contribute to maintaining skin integrity. Skin cleanliness and the prevention of skin breakdown is vital (Voegeli 2008a), and equally important is the enhancement of comfort and well-being, a notion that Ong 1998 describes as the ‘look good - feel good’ factor.

The majority of people regularly wash or bathe independently (Evans 2004). However, older people may experience increasing difficulties in completing their usual personal hygiene activities independently. Skin care is “one of the core elements of care in all fields of nursing” (Coddell 2013), and personal hygiene is an important component of this. Older people may prefer not to request help with personal hygiene, and it is important that such requests do not equate with loss of dignity (ANA 2001; DH 2006). Care should focus on educating older people about optimal but manageable routine skin care and enabling them to remain as independent as possible.

It is argued that current practice in personal hygiene is largely based on ‘tried and tested practice’ (Lentz 2003) as the evidence base is poorly developed (Hodgkinson 2007; Holloway 2005). In a recent systematic review of evidence-based skin care for older people, Kottner 2013 and colleagues concluded that little is known about the relative benefits of different cleansing and moisturising regimens for older people. Lentz 2003 suggests that existing practices may be injurious to skin health. In an experimental cohort study of washing with soap and water and towel drying, Voegeli 2008b found that this process causes significant disruption to skin barrier function. Guidelines for providing personal care exist (for example, Dougherty 2008; Downey 2008) with varying degrees of underpinning evidence. There is some consensus on recommended practices in providing personal hygiene care; however, this is largely based on clinical experience. We have listed these guidelines in Table 2.

It is possible that current nursing care in hospitals and residential homes might be damaging the skin of older patients because of well-intentioned but too frequent washing. It is essential that there is a balance between maintaining health and well-being through meeting personal hygiene needs and not over-cleansing the skin and thus potentially compromising barrier function (Voegeli 2008a). It is well recognised that nursing and care staff strive to ensure that patients’ skin is maintained in a clean, dry, and comfortable state. It is suggested that nurses tend to feel that if patients are not bathed at least daily, they are ‘not doing their job properly’ (Lentz 2003). Whilst maintaining hygiene is essential, over-washing, particularly with harsh products, can result in impaired skin integrity (Gardiner 2008).

Skin breakdown can have a devastating effect on the older person and cause distress to both them and their carers. It is clinically challenging, and has the potential to cause significant morbidity (Farage 2007) and lead to diminished quality of life. It can lead to increased lengths of stay in hospital and higher levels of depen-

dence in residential homes, and be a burden on acute and community care (Gardiner 2008).

Although it is commonly assumed that older people are less susceptible to the psychosocial impact of skin problems, studies by Harlow 2000 and Shah 2006 indicate that this is not the case. It is well recognised that older people with skin conditions are likely to endure unpleasant symptoms, such as pain and itch, social stigma, and cosmetic disfigurement (Shah 2006). Equally, it has been demonstrated that people with specific conditions, including leg ulcers (Hyde 1999) and pressure ulcers (Gorecki 2010), experience significant burden and decreased health-related quality of life. Evidence-based skin hygiene practices have the potential to prevent the precursor to skin breakdown, namely, damage to skin integrity.

Description of the intervention

There are numerous skin cleansing and emolliating products available, although few have been developed specifically for older people.

Cleansers

Skin cleansers are available globally in varying forms, including bars, liquids, gels, and creams, to be used in combination with water. The type of surfactant (the key cleansing ingredient) used has an effect on the mildness or otherwise of the product (Abbas 2004). The major groups of surfactant are natural and synthetic. Natural surfactants (soaps) are the most common cleansing agents. Some products, for example, superfatted soaps, transparent soaps, and combination bars, have components to reduce irritancy (Abbas 2004). Alternatives to soap-based cleansers include synthetic surfactant-based syndet (synthetic detergent) products (for example, Dove) (Abbas 2004) and emollient-rich bath additives and shower preparations. There are also some prepackaged specialist bed bath wipes, which contain premoistened cloths with evaporating no-rinse cleansers and emollients (Massa 2010), for example, Bag-Bath® (ApodanUSA) and Oasis™ Bed Bath System (Synergy Health).

Drying

After cleansing with water and a cleansing agent, drying of the skin is essential and is generally achieved by towel drying using either a rubbing or patting action. Towel drying incurs the risk of direct mechanical damage to the stratum corneum; however, if the skin is not dried thoroughly, there is a risk of over-hydration and maceration (Voegeli 2010). No skin drying is required after the use of bed bath wipes.

Emollients

Simple emollients are skin moisturisers that leave a barrier of artificial lipids, such as petrolatum or mineral oil, on the skin surface, thus, trapping water into the stratum corneum (SC) (reducing transepidermal water loss) (Danby 2011a). The consistency and occlusive properties of the emollient depends on the levels of lipid or oil and water, which underpins the categorisation of emollients as ointments, creams, or lotions. Ointments have the least amount of water and the most lipids and therefore exhibit greater skin occlusion. Creams contain similar amounts of water and oil and are more easily spread across the skin compared with ointments, making them more cosmetically acceptable. To emulsify the lipid and aqueous phases of an emollient, surfactants are required. As with cleansers, a wide range of different surfactants are used to emulsify emollients, the choice of which affects the irritant potential of the formulation (Cork 2003). Ingredients, such as humectants, physiological lipids, and antipruritic agents, can be added to emollient bases (Moncrieff 2013). Humectants, including urea, attract and trap water in the stratum corneum (Loden 2012). This can off-set the reduced levels of natural moisturising factor (NMF) and other natural moisturising agents in dry and older skin (White-Chu 2011). Likewise, natural lipids, for example, ceramides, cholesterol, and free fatty acids, which are found in the stratum corneum, return the defective intercellular lipid matrix (Chamlin 2002). Some natural humectants and lipids have also been found to exhibit biological activity promoting the expression of key structural proteins required for a healthy skin barrier (Grether-Beck 2012; Schrader 2012). Lauromacrogols are added to some products for their local anaesthetic and antipruritic action (Betzuege 2005).

In addition to topical leave-on emollients, a range of emollient-based soap substitutes and bath emollients are available. These emollient wash products are designed to substitute harsh cleansers and minimise dryness induced by washing (Cork 1998). The use of topical emollients in combination with emollient wash products is referred to as complete emollient therapy.

Many cleansers and emollients are available to the public without need for a healthcare consultation. The ideal washing and emolliating intervention is one that removes oils and dirt from the skin whilst avoiding dryness or irritation to the skin, and which maintains or promotes skin integrity and comfort. The intervention should have minimal adverse effects, and products should be acceptable to the person using them to ensure compliance (Coddell 2010).

How the intervention might work

Hygiene interventions

Cleansers

The purpose of skin cleansing is to remove dirt, soil, and bacteria from the skin; however, this action typically leads to weakening of skin barrier function (Subramanyan 2004). The type of surfactant used may influence the severity of damage to the stratum corneum (Gloor 2004). Soap-based products are more damaging to the skin than syndets (Barel 2001). The surfactants in all cleansers can cause immediate after-wash tightness (Kawai 1984), dryness (Imokawa 1989) and barrier damage, erythema, and irritation and itch (Wilhelm 1994). Soaps and detergents can increase pH of the stratum corneum, which enhances protease activity and inhibits lipid lamellae synthesis. In combination, this can lead to breakdown of skin barrier function (Cork 2009). Surfactant residues may form an irritant reservoir on the skin, even after rinsing (Loden 2003). This potential skin barrier disruption is a particular issue for older people, who are likely to already have dry and fragile skin. Milder cleansing formulations are designed to interact minimally with the stratum corneum structure, but function effectively as cleansers (Subramanyan 2004). These milder cleansing formulations may minimise damage to skin integrity and increase a person's comfort.

Drying

When using any cleansing preparation with water, skin drying is essential using either a patting or rubbing action. Bed bath wipes obviate the need for drying, relying instead on evaporation.

Emollient interventions

Emollients

Most emollients, such as petrolatum, which are biologically inert, are used regularly to temporarily restore the hydration of the skin, "which is recommended to be approximately 500g per week for adults" (Darsow 2009). Aged skin is particularly prone to dryness, which can lead to the development of superficial cracks that allow irritants and allergens into the skin (Van Onselen 2011). Pruritus caused by irritants creates the desire to scratch, which then causes further damage to the skin in a viscous, escalating cycle (the itch-scratch cycle) (Cork 1997). The use of emollients is linked with reduction in skin dryness and pruritus and improvement in skin barrier function (Darsow 2009). Yet, the eczema task force 2009 position paper on diagnosis and treatment of eczema concluded that there is currently a limited evidence base for the use of emollients (Darsow 2009). However, randomised controlled trials published in recent years suggest that the use of certain 'complex' emollients can be steroid-sparing, reduce the severity of eczema, and delay relapse of the condition (Simpson 2010; Wren 2009). Importantly, emollients are not all the same, and depending on their formulation, they can have very different effects on the skin.

The inclusion of a humectant, such as urea or lactate, in an emollient formulation is associated with significantly improved stratum corneum hydration (Loden 2012). Aqueous cream BP, a traditional emollient containing no humectant, is poorly hydrating compared with humectant emollients (Brown 2013). Furthermore, the use of aqueous cream BP as a topical emollient was found to damage the skin barrier, an effect associated with the presence of the harsh anionic surfactant sodium lauryl sulphate (SLS) in its formulation (Danby 2011b; Mohammed 2011; Tsang 2010). The negative effects of aqueous cream BP on the skin barrier helps explain why 56% of children using this emollient developed adverse skin reactions in an audit conducted in 2003 (Cork 2003).

The contrasting effects of some emollients on the skin, with the potential for harm in some cases, highlight the need for further evidence to support best practice in skin care. Not only do emollients reduce the level of dry skin, they are now thought to be a promising intervention for the prevention of skin conditions like atopic dermatitis and asteatotic eczema, which is due to very dry skin (Williams 2012). The role of emollient wash products in treatment and prevention of dry skin conditions is still unclear because of a lack of clinical evidence (Tarr 2009).

Interventions aim to maintain and enhance skin integrity and skin barrier function. Outcome measures provide evidence of the effect of interventions; technical measures include the following:

- Biophysiological measures of skin integrity
 - Transepidermal water loss (TEWL). This is a validated measure of inside to outside stratum corneum (SC) permeability barrier function. TEWL correlates with skin barrier dysfunction and disease severity in atopic dermatitis (Fluhr 2006a).
 - Stratum corneum hydration (SCH). Stratum corneum hydration is routinely measured indirectly using probes of capacitance or conductance (Heinrich 2003). Other measures may include near and mid-IR (infrared) spectroscopy and other imaging techniques. Dry skin (low SCH) is prone to superficial cracking leading to the penetration of irritants.
 - Corneosurfametry (CSM). This is an *ex vivo* test performed on superficial samples of SC collected with adhesive discs to quantify the irritant potential of cleansers (Pierard 1995).
 - Skin surface pH measured with a flat pH electrode (Fluhr 2006b). Skin surface pH is increased in aged and xerotic skin. Normal skin surface pH of around 5.0 is required for normal skin barrier function and to maintain normal microbial flora. Increased skin surface pH leads to skin barrier breakdown and a preferential environment for pathogenic bacteria.
- Biochemical markers of skin integrity
 - Resident microbes (microbiome analysis). The microbial barrier plays an important role in maintaining normal skin function.
 - Types and concentration of stratum corneum lipids. The lipid composition of the stratum corneum determines its barrier function and integrity (Ghadially 1995; Rogers 1996).

Why it is important to do this review

Experts in dermatology nursing (Ersner 2005; Voegeli 2005) have examined the issue of skin vulnerability in older people. Maintaining skin hygiene and preserving or improving skin barrier function is an essential part of ensuring health and well-being for older people (Pegram 2007), particularly those in care environments, such as hospitals and residential settings. This is an area of substantial concern to those people affected, their families, and healthcare providers, with significant implications for healthcare systems worldwide. There has been significant research about secondary and tertiary prevention in skin care, such as management of incontinence and pressure ulcer prevention. However, few studies have addressed primary prevention - the maintenance of skin integrity through 'routine' skin hygiene practices. At present, most care is based on 'tried and tested' practice, rather than on a firm evidence base.

This review is needed to identify gaps in current knowledge and thus inform the future research agenda, leading to rigorously developed and contextually appropriate guidelines, which take into account effectiveness, cost-effectiveness, and acceptability to those affected and their healthcare practitioners (Gardiner 2008) and to provide a firm foundation for future health-care practice.

OBJECTIVES

To assess the effects of hygiene and emollient interventions for maintaining skin integrity in older people in hospital and residential care settings.

METHODS

Criteria for considering studies for this review

Types of studies

We will consider all randomised controlled trials of hygiene and emollient interventions. We will exclude quasirandomised trials.

Types of participants

Men and women aged ≥ 60 years who are in hospital or residential care settings.

Types of interventions

We will seek studies comparing populations of older people testing the following (and combinations thereof) over a fixed time period.

- Hygiene practices, including the following:
 - hygiene delivery methods (for example, immersion bath versus bed bath versus strip wash versus shower); frequency of hygiene practices (for example, daily, weekly); and types and dosages (for example, water only versus soap and water versus other skin cleansers).
- Emollient regimens, including the following:
 - method of application (for example, bath or shower products or leave-on emollients); types and dosages (for example, lotions, creams, ointments, and number of grams per application); and frequency of use (for example, once daily, twice daily, or more frequently).

Comparison 1: Hygiene interventions versus no interventions or standard practices.

Comparison 2: Emollient regimens as described above versus placebo, no intervention, or standard practices.

Types of outcome measures

The following outcomes are of interest to us in any combination as measured by clinician, participant, carer, or other outcome observer.

Primary outcomes

1. Frequency of skin damage (dryness or eczema on the Skin Condition Form as assessed by an observer).
2. Side-effects from intervention, frequency of cutaneous reaction (irritant or allergic) to intervention (emollient or cleanser use).

Secondary outcomes

1. Transepidermal water loss (TEWL).
2. Stratum corneum hydration (SCH).
3. Erythema (redness) (subjective assessment of erythema as performed clinically, objective assessment as measured using a chromameter).
4. Clinical score of dryness.
5. Clinical score of itch.

Tertiary outcomes

1. Corneosurfametry (CSM).
2. Skin surface pH measured with a flat pH electrode.
3. Resident microbes (microbiome analysis).
4. Types and concentration of SC lipids.

We will accept outcome measures however measured, although this will be accompanied by a critical evaluation of the rigour of the measures used, with attention to reliability and validity issues.

Search methods for identification of studies

We aim to identify all relevant randomised controlled trials (RCTs) regardless of language or publication status (published, unpublished, in press, or in progress).

Electronic searches

We will search the following databases for relevant trials:

- the Cochrane Skin Group Specialised Register;
- the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library*;
- MEDLINE via OVID (from 1946);
- Embase via OVID (from 1974); and
- CINAHL (Cumulative Index to Nursing and Allied Health Literature) via EBSCO (from 1981).

We have devised a draft search strategy for randomised controlled trials (RCTs) for MEDLINE (OVID), which is displayed in [Appendix 1](#). This will be used as the basis for search strategies for the other databases listed.

Searching other resources

Trials registers

We will search the following trials registers.

- The metaRegister of Controlled Trials (www.controlled-trials.com).
- The US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov).
- The Australian New Zealand Clinical Trials Registry (www.anzctr.org.au).
- The World Health Organization International Clinical Trials Registry platform (www.who.int/trialsearch).
- The EU Clinical Trials Register (www.clinicaltrialsregister.eu).

Searching other resources

References from published studies

We will check the bibliographies of included and excluded studies for further references to relevant trials.

Unpublished literature

We will obtain unpublished and grey literature via correspondence with authors, major pharmaceutical companies, and the Open-Grey database (formerly System for Information on Grey Literature, or SIGLE) in Europe.

Adverse effects

We will not perform a separate search for adverse effects of the target interventions. However, we will examine data on adverse effects from the included studies we identify.

Data collection and analysis

We plan to include at least one 'Summary of Findings' table in our review. In this, we will summarise the primary outcomes for the most important comparison. If we feel there are several major comparisons or that our findings need to be summarised for different populations, we will include further 'Summary of Findings' tables.

Please note that some parts of the methods section of this review uses text that was originally published in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Selection of studies

We will only include randomised controlled trials (RCT). Two review authors will check titles and abstracts identified from the searches (FC and YJ). If it is clear that the study does not refer to an RCT on hygiene and emollient practices for older people in hospital or residential care settings, we will exclude it. If unclear, we will obtain the full text of the study for independent assessment by two review authors (FC and YJ). The same two review authors will decide by consensus which trials fulfil the inclusion criteria. In the event of disagreement, a third review author will assess the full text. If we identify suitable papers written in languages other than English, we will make realistic attempts to obtain an accurate English language translation. We will list in the 'Characteristics of excluded studies' tables of the review any studies that are initially thought to meet the eligibility criteria but which we then subsequently exclude.

Data extraction and management

Two review authors (FC and YJ) will independently extract data from the included studies using a data collection form, which they will pilot test prior to use. The two authors will resolve by discussion any differences that arise in the data extraction. If no agreement is reached, we will consult a third review author. Data collected will include details about the participants, study design, 'Risk of bias' assessment, interventions, outcomes, and results.

Assessment of risk of bias in included studies

Two authors (EG and YJ) will independently assess all included studies for risk of bias. They will do this using the risk assessment tool in the *Cochrane Handbook for Systematic Review of Interventions* (Higgins 2011). For each study, they will make an assessment on the risk of bias using the domains listed below. They will assess each domain as 'low' (low risk of bias), 'high' (high risk of bias), or 'unclear' (unclear risk of bias). In the event of a discrepancy between the two review authors on a particular judgment, a discussion will take place. In the event of continuing disagreement, they will consult a third review author.

If the information in a study is not clear enough to make a judgment, we will seek clarification from the study authors in question. We will use aids from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) to assess the risk of bias. We will include details of bias in a 'Risk of bias' table for each included study in the review. We will look at the following areas.

i. Selection bias

Sequence generation

For each study, we will describe the means of sequence generation in order to assess if it was appropriate enough for the risk of bias to be low.

Following Jüni 2001, we will consider the risk of bias to be low if the sequence was generated in an unpredictable manner (e.g., a programme to generate random numbers) and unclear if there is insufficient information to be able to make a judgement of whether it is low risk of bias or it refers to some systematic but non-random approach.

Allocation concealment

We will also describe the details of how allocation concealment was carried out and make an assessment about whether allocation may have been foreseen before or during participant recruitment. For example, we will consider the risk of bias to be low if the randomisation was carried out independently (Jüni 2001) and high if the allocations were given from a list on a sheet of paper on a trial investigator's desk.

ii. Performance bias

Blinding of participants and personnel

We will describe for each included study all methods used to blind participants and study personnel. For example, if an included study compared a control emollient with an intervention emollient and reported that blinding was achieved by use of identical packaging,

we will assess the risk of performance bias as low. If blinding has not occurred, we will make an assessment as to whether this might have introduced bias.

iii. Detection bias

Blinding of outcome assessment

We will look at whether or not outcome assessors in study trials were blinded to the intervention. We will give an included study a low 'Risk of bias' judgment if a clear description of measures taken to prevent contact between staff delivering the intervention or control treatment and those assessing outcome and analysing trial data was given. On the other hand, if there is evidence of contact between these staff groups and this lack of blinding was also likely to affect the outcome measurement process, we will give a high 'Risk of bias' judgment.

iv. Attrition bias

Incomplete outcome data

We will examine studies for incomplete outcome data. In each study, we will state the number of trial participants in each intervention group and compare this with the number of randomised participants overall. We will state whether or not any excluded data or withdrawn participants have been reported and the reasons for this where applicable. We will use the guidance in Section 8.5 of Higgins 2011 to classify studies. For example, if outcome data are missing for administrative reasons, this is unlikely to be related to the unobserved outcome measurements, and we will make a low 'Risk of bias' judgment.

v. Reporting bias

Selective reporting

We will examine each study for the possibility of selective reporting. As in the previous subsection, we will use the guidance in Section 8.5 of Higgins 2011 to classify studies. For example, if there is evidence that all outcomes the study authors planned to measure have been reported, we will make a low 'Risk of bias' judgment. However, if some planned outcomes have been reported incompletely or not at all, we will make a high 'Risk of bias' judgment.

vi. Additional sources of bias

We do not anticipate any additional sources of bias to those listed above.

Measures of treatment effect

We will report means and standard deviations for continuous outcome measures and percentages of successful outcomes for dichotomous outcome measures. If we can directly combine the studies included in the review, we will use the meta-analysis techniques discussed in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We intend to use odds ratios as measures of treatment effect for dichotomous outcome measures. We intend to use mean differences or standardised mean differences (subject to the cautionary caveats in Higgins 2011, Section 9.4.5.1) for continuous outcome measures.

Unit of analysis issues

If studies include a within-patient trial (e.g., different interventions are used for different parts of the body), we will use methods that take the within-patient pairing into account. In the event of the inclusion of any cross-over trials in the review, if possible, we will obtain measures of treatment effect based on a paired t-test. We will not combine these results with results from parallel group trials.

We might also include studies that used cluster randomisation, e.g., with care homes or hospital wards used as clusters. We might combine results from cluster randomised studies together in a meta-analysis. We will not combine results from cluster randomised studies with results from parallel group trials in case such studies differ in other ways apart from study design.

Dealing with missing data

In the event of missing data being substantial enough for studies to be classified as high risk of bias or the need to clarify particular issues, we will contact the authors of the studies in question. If necessary, we will undertake a sensitivity analysis to examine the impact on the overall treatment effect where attempts to obtain further details from the original study authors have been unsuccessful. This would involve conducting a meta-analysis twice, first with all studies included using an available case analysis and then omitting the studies with higher levels of potential bias including attrition bias arising from missing data.

Assessment of heterogeneity

Assuming outcome measures from included studies are potentially comparable in the first place (please see the [Data synthesis](#) section), we will test for heterogeneity of the intervention effect by using the I^2 statistic, as recommended in Chapter 9 of Higgins 2011. In the event of substantial heterogeneity (please see the [Data synthesis](#) section), we will assess whether this is due to a single 'outlier' study. If this is the case, we will perform and report meta-analyses both with and without this study. If there are no obvious outlying studies, we will try to establish the reasons for heterogeneity and come to a decision on the viability of a meta-analysis.

Assessment of reporting biases

We will assess publication bias using funnel plots if we include at least 10 studies (following the recommendation in Chapter 10 of Higgins 2011) and a meta-analysis is feasible. We will bear in mind the caveats associated with the use of funnel plots. If asymmetry is found, we will consider publication bias as one possible cause.

Data synthesis

We will first of all assess whether each of our outcomes of interest are measured in a large enough subset of studies for a meta-analysis to be viable (i.e., the clinical diversity is not too great). We will also assess whether the intervention and control groups in each study and the study designs are sufficiently consistent for us to synthesise a global 'hygiene or emollient practice versus control' effect (i.e., the methodological diversity is not too great). If there is not too much diversity, we will then compare outcome measures across studies for each outcome of interest. We will use the meta-analysis techniques in Chapter 9 of Higgins 2011 for combining outcome measures on different scales, provided that there is no evidence that some study populations are genuinely more variable than others. We will then test for the heterogeneity of the intervention effect as described above. If substantial diversity or (statistical) heterogeneity is identified between studies or the number of included studies is very small, we will not perform a meta-analysis but instead present a narrative analysis that includes details of study results, trial interventions, and study design. If studies are pooled, we plan to use a fixed-effect meta-analysis. We will not pool study data if the I^2 statistic is greater than 50% and this is not due to a single 'outlier' study (please see the [Assessment of heterogeneity](#) section).

Where results are estimated for individual studies with low numbers of outcomes (< 10 in total) or where the total sample size is less than 30 participants, we will report the proportion of dichotomous outcomes in each treatment group together with a P value from a Fisher's exact test.

Subgroup analysis and investigation of heterogeneity

As reported above, we will assess heterogeneity using the I^2 statistic. We are expecting to include only a small number of studies (10 or fewer) and do not plan to do any subgroup analyses involving study-level covariates.

Sensitivity analysis

In the event that we decide to use a meta-analysis and that some studies are found to have higher levels of potential bias when the 'Risk of bias' checklist is applied, we will perform a sensitivity analysis. This would involve conducting a meta-analysis twice, first with all studies included and then omitting the studies with high risk of bias for any of the five assessed domains and assessing how much this changes the overall estimate of intervention effect.

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* Indicates the major publication for the study

ADDITIONAL TABLES

Table 1. Intrinsic changes that occur in ageing skin

Intrinsic skin change	Effect on skin
Reduction in skin cell turnover (Finch 2003) Skin gradually becomes more fragile as the epidermis thins and there is a reduction in integrity between epidermis and dermis (Ward 2005)	Papery appearance Less effective barrier More prone to mechanical injury and damage from moisture, friction, and trauma
Reduction in key stratum corneum metabolites, including components of natural moisturising factor and the lipid lamellae (Ghadially 1995; Harding 2000; Rogers 1996)	Decreased stratum corneum hydration and reduced integrity
Blood vessels become more fragile (Fore 2006). Blood supply to the skin is reduced	Skin becomes more prone to bruising and damage
Collagen fibres that provide structural support stiffen (Nazarko 2005) Elastic fibres thicken (Finch 2003)	Creases and wrinkles form More prone to tearing and shearing
Production of sebum decreases (Finch 2003)	Skin becomes more dry Vulnerable to splitting, cracking, and infection Sensitivity to irritants increases
Sweat glands become smaller and secrete less sweat (Ersser 2009)	Skin becomes more dry Less effective temperature control
Localised overproduction of melanin (Finch 2003)	Blotchiness and uneven pigmentation
Reduction in subcutaneous fat (Burr 2005)	Less protection and insulation
Reduction in sensory receptors (Finch 2003)	Less sensitivity, so more risk of inadvertent damage

The content of this table has previously been published in Cowdell 2011.

Table 2. Personal hygiene guidelines based on clinical experience

Intervention	Rationale
Bathe regularly (Lawton 2007)	Keeps skin clean and reduces risk of infection Good for self-esteem, image, and relaxation Promotes well-being
Use warm rather than hot water (Lawton 2007)	Reduce risk of dehydrating skin
Do not soak for too long (Lawton 2007)	Reduce risk of dehydrating skin

Table 2. Personal hygiene guidelines based on clinical experience (Continued)

Do not over wash (BAD 2006)	May cause itching and dryness
Avoid soap; use emollients or other gentle products (Ronda 2002)	Maintain pH balance of skin Soaps and detergents can increase skin pH, which can cause further breakdown of skin barrier
Use a soft cloth (Ronda 2002)	Avoids damage by abrasion
Pat or gently rub skin dry (Ersser 2005)	Avoids damage by abrasion
Use products that are acceptable to the person (Lawton 2007)	Increases concordance and cost effectiveness

The content of this table has previously been published in Cowdell 2011.

APPENDICES

Appendix I. Draft MEDLINE (Ovid) search strategy

1. exp Baths/
2. bath\$3.ti,ab.
3. strip wash\$3.ti,ab.
4. shower\$.ti,ab.
5. towel\$.ti,ab.
6. wash\$3.ti,ab.
7. exp Soaps/
8. soap\$.ti,ab.
9. clean\$4.ti,ab.
10. cleanliness.ti,ab.
11. wipe\$1.ti,ab.
12. exp Emollients/
13. emollient\$.ti,ab.
14. (moisturiz\$ or moisturiz\$).ti,ab.
15. lotion\$.ti,ab.
16. cream\$.ti,ab.
17. ointment\$.ti,ab.
18. exp Water/
19. water.ti,ab.
20. exp Hygiene/
21. exp Skin Cream/
22. exp Skin Care/
23. or/1-22
24. skin integrity.ti,ab.
25. skin.ti,ab.

26. exp *Skin/
27. xerosis.ti,ab.
28. fissures.ti,ab.
29. pruritus.ti,ab. or exp Pruritus/
30. itch\$.ti,ab.
31. (skin adj3 dry\$).ti,ab.
32. or/24-31
33. exp Aged/
34. (aged or elderly or geriatric).ti,ab.
35. 33 or 34
36. (doubl\$ adj blind\$).ti,ab.
37. (singl\$ adj blind).ti,ab.
38. random\$.ti,ab.
39. randomized controlled trial.pt.
40. controlled clinical trial.pt.
41. randomized.ab.
42. placebo.ab.
43. clinical trials as topic.sh.
44. randomly.ab.
45. trial.ti.
46. or/36-45
47. exp animals/ not humans.sh.
48. 46 not 47
49. 23 and 32 and 35 and 48

WHAT'S NEW

Date	Event	Description
12 October 2016	Amended	Lead (and contact) author information (affiliation) updated

CONTRIBUTIONS OF AUTHORS

FC was the contact person with the editorial base.

FC co-ordinated the contributions from the co-authors and wrote the final draft of the protocol.

All authors worked on the methods sections.

FC, YJ, SD, MC, and SL drafted the clinical sections of the background and responded to the clinical comments of the referees.

YJ, SD, EG, and FC responded to the methodology and statistics comments of the referees.

All authors contributed to writing the protocol.

AR was the consumer co-author and checked the protocol for readability and clarity. She also ensured that the outcomes are relevant to consumers.

FC and YJ are the guarantors of the final review.

Disclaimer

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health, UK.

DECLARATIONS OF INTEREST

Fiona Cowdell: Nothing to declare.

Yuri Jadotte: Nothing to declare.

Steven Ersser: Nothing to declare.

Simon Danby “I have received investigator-led research funding from Astellas Pharma Europe, Stiefel, a GSK company, Johnson & Johnson, and Almirall, which manufacture topical treatments for skin conditions; honoraria for speaking at conferences from Astellas and Almirall; and consultancy fees from Almirall for services as a scientific writer.”

Shernaz Walton: Nothing to declare.

Sandra Lawton: “I have been on an advisory board for Almirall and received an honorarium for speaking at meetings for Genus, Almirall and Thornton & Ross Ltd. All are emollient companies, and no further work is planned with these companies.”

Amanda Roberts: Nothing to declare.

Eric Gardiner: Nothing to declare.

Fiona Ware: Nothing to declare.

Michael Cork: “I have received funding/research grants/fees for lecturing and advisory board membership from Almirall; Merck & Co., Inc.; and Stiefel, a GSK company.”

Mrs Mary Haynes, clinical referee, declared the following: “I have been on an advisory board for Johnson & Johnson UK - Aveeno®; I helped Genus in the production of an educational video for Eczmol; and I have received an honorarium for speaking at educational meetings by GlaxoSmithKline.”

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