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## Hygiene and emollient interventions for maintaining skin integrity in older people in hospital and residential care settings (Review)

Cowdell F, Jadotte YT, Ersser SJ, Danby S, Lawton S, Roberts A, Dyson J

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[Intervention Review]

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

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## ABSTRACT

### Background

Ageing has a degenerative effect on the skin, leaving it more vulnerable to damage. Hygiene and emollient interventions may help maintain skin integrity in older people in hospital and residential care settings; however, at present, most care is based on "tried and tested" practice, rather than on evidence.

### Objectives

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

### Search methods

We searched the Cochrane Skin Specialised Register, CENTRAL, MEDLINE, Embase, and CINAHL, up to January 2019. We also searched five trials registers.

### Selection criteria

Randomised controlled trials comparing hygiene and emollient interventions versus placebo, no intervention, or standard practices for older people aged ≥ 60 years in hospital or residential care settings.

### Data collection and analysis

We used standard methodological procedures as expected by Cochrane. Primary outcomes were frequency of skin damage, for example, complete loss of integrity (tears or ulceration) or partial loss of integrity (fissuring), and side effects. Secondary outcomes included transepidermal water loss (TEWL), stratum corneum hydration (SCH), erythema, and clinical scores of dryness or itch. We used GRADE to assess the quality of evidence.

## Main results

We included six trials involving 1598 residential care home residents; no included trial had a hospital setting. Most participants had a mean age of 80+ years; when specified, more women were recruited than men. Two studies included only people with diagnosed dry skin. Studies were conducted in Asia, Australasia, Europe, and North America. A range of hygiene and emollient interventions were assessed: a moisturising soap bar; combinations of water soak, oil soak, and lotion; regular application of a commercially available moisturiser; use of two different standardised skin care regimens comprising a body wash and leave-on body lotion; bed bath with “wash gloves” containing numerous ingredients; and application of a hot towel after usual care bed bath.

In five studies, treatment duration ranged from five days to six months; only one study had post-treatment follow-up (one to eight days from end of treatment). Outcomes in the hot towel study were measured 15 minutes after the skin was wiped with a dry towel.

Three studies each had high risk of attrition, detection, and performance bias.

Only one trial (n = 984) assessed frequency of skin damage via average monthly incidence of skin tears during six months of treatment. The emollient group (usual care plus twice-daily application of moisturiser) had 5.76 tears per month per 1000 occupied bed-days compared with 10.57 tears in the usual care only group (ad hoc or no standardised skin-moisturising regimen) (P = 0.004), but this is based on very low-quality evidence, so we are uncertain of this result.

Only one trial (n = 133) reported measuring side effects. At 56 ± 4 days from baseline, there were three undesirable effects (itch (mild), redness (mild/moderate), and irritation (severe)) in intervention group 1 (regimen consisting of a moisturising body wash and a moisturising leave-on lotion) and one event (mild skin dryness) in intervention group 2 (regimen consisting of body wash and a water-in-oil emulsion containing emollients and 4% urea). In both groups, the body wash was used daily and the emollient twice daily for eight weeks. There were zero adverse events in the usual care group. This result is based on very low-quality evidence. This same study also measured TEWL at 56 ± 4 days in the mid-volar forearm (n = 106) and the lower leg (n = 105). Compared to usual care, there may be no difference in TEWL between intervention groups, but evidence quality is low.

One study, which compared application of a hot towel for 10 seconds after a usual care bed bath versus usual care bed bath only, also measured TEWL at 15 minutes after the skin was wiped with a dry towel for one second. The mean TEWL was 8.6 g/m<sup>2</sup>/h (standard deviation (SD) 3.2) in the hot towel group compared with 8.9 g/m<sup>2</sup>/h (SD 4.1) in the usual care group (low-quality evidence; n = 42), showing there may be little or no difference between groups. A lower score is more favourable.

Three studies (266 participants) measured SCH, but all evidence is of very low quality; we did not combine these studies due to differences in treatments (different skin care regimens for eight weeks; wash gloves for 12 weeks; and single application of hot towel to the skin) and differences in outcome reporting. All three studies showed no clear difference in SCH at follow-up (ranging from 15 minutes after the intervention to 12 weeks from baseline), when compared with usual care. A clinical score of dryness was measured by three studies (including 245 participants); pooling was not appropriate. The treatment groups (different skin care regimens for eight weeks; a moisturising soap bar used for five days; and combinations of water soak, oil soak, and lotion for 12 days) may reduce dryness compared to standard care or no intervention (results measured at 5, 8, and 56 ± 4 days after treatment was initiated). However, the quality of evidence for this outcome is low.

Outcomes of erythema and clinical score of itch were not assessed in any included studies.

## Authors' conclusions

Current evidence about the effects of hygiene and emollients in maintaining skin integrity in older people in residential and hospital settings is inadequate. We cannot draw conclusions regarding frequency of skin damage or side effects due to very low-quality evidence.

Low-quality evidence suggests that in residential care settings for older people, certain types of hygiene and emollient interventions (two different standardised skin care regimens; moisturising soap bar; combinations of water soak, oil soak, and lotion) may be more effective in terms of clinical score of dryness when compared with no intervention or standard care.

Studies were small and generally lacked methodological rigour, and information on effect sizes and precision was absent. More clinical trials are needed to guide practice; future studies should use a standard approach to measuring treatment effects and should include patient-reported outcomes, such as comfort and acceptability.

## PLAIN LANGUAGE SUMMARY

### What effects do washing and moisturising practices have on the skin health of older people in hospital and residential care settings?

#### Review question

We reviewed evidence about the effects of different washing practices and emollients (moisturisers) when compared with usual care or no treatment on maintaining healthy skin in people aged 60 years or older in hospitals or care homes.

#### Background

**Hygiene and emollient interventions for maintaining skin integrity in older people in hospital and residential care settings (Review)**

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With age, skin becomes drier; this may lead to discomfort, itching, and skin damage. Good hygiene and moisturising practice supports healthy skin ageing. However, research is limited, and current care is largely based on custom and practice.

### Study characteristics

We included six studies (1598 participants), all completed in care homes. When reported, most participants were female and aged 80 years or older.

Two studies included only people with diagnosed dry skin. Studies compared usual care or no treatment against differing cleansing and moisturising skin care regimens (a moisturising soap bar; combinations of water soak, oil soak, and lotion; regular application of a commercially available moisturiser; use of two different standardised skin care regimens comprising a body wash and leave-on body lotion; bed bath with "wash gloves" containing numerous ingredients; and application of a hot towel after usual care bed bath). Length of treatment ranged from a single application for 10 seconds to six months of twice-daily moisturiser use. Only one study assessed participants post treatment (one to eight days post treatment), and participants in the hot towel study were measured 15 minutes after their skin was wiped with a dry towel. When reported, four studies had received external funding, in two cases from commercial sponsors.

The evidence is current to January 2019.

### Key results

Our main outcomes were skin damage and treatment side effects. Only one study reported frequency of skin damage (skin tears), finding fewer tears per month (5.76 per 1000 occupied bed-days) with usual care plus twice-daily application of a commercially available, pH-neutral moisturising lotion (for six months) compared with usual care (i.e. no standardised skin-moisturising routine) (10.57 tears). However, this is based on very low-quality evidence, so we are uncertain about this result.

Only one study measured side effects of treatments, comparing care as usual (i.e. usual personal hygiene and care products) against the use of two different types of moisturising body wash plus body lotion (application was twice daily for eight weeks) in two groups of participants. Four side effects were reported in the treatment group (assessment occurred approximately 56 days after treatment started): itch (mild), redness (mild/moderate), irritation (severe), and mild skin dryness. No side effects were reported in the care-as-usual group. However, this finding is based on very low-quality evidence, meaning that we are uncertain about this result.

The same study assessed water loss from the skin of the forearm and lower leg and found there may be no difference between usual care and treatment. A different study compared a hot towel applied for 10 seconds after a usual care bed bath versus usual care bed bath only, finding there may be little or no difference in water loss between groups. Both studies are based on low-quality evidence.

Three studies, which assessed different skin care regimens for eight weeks; use of wash gloves for 12 weeks; and single application of a hot towel, showed no clear difference in hydration of the stratum corneum (the outermost layer of the skin) when compared with usual care. However, evidence quality was very low, so we are uncertain of this result.

Three studies measured skin dryness and there may be improvement with the following treatments compared to standard care or no intervention: different skin care regimens for eight weeks; a moisturising soap bar used for five days; and combinations of water soak, oil soak, and lotion for 12 days (all low-quality evidence).

No included studies assessed skin redness and clinical score of itch.

### Quality of the evidence

Evidence quality for outcomes of skin damage, side effects, and moisture in the outermost skin layer was very low. For remaining measured outcomes (i.e. water loss from the skin and skin dryness), evidence quality was low. We had concerns about how the studies were designed and undertaken, and about this review's small numbers of studies and participants.

## SUMMARY OF FINDINGS

### Summary of findings for the main comparison. Summary of findings for primary and secondary outcomes

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

**Patient or population:** people 60 years of age and older

**Setting:** residential care

**Intervention:** hygiene and emollient regimens

[Boccanfuso 1978](#): a moisturising soap bar

[Carville 2014](#): 'usual' care + twice-daily application of a commercially available, standardised pH (5-6) neutral, perfume-free moisturiser

[Gillis 2016](#): usual care (traditional bed bath) using "wash gloves"

[Hahnel 2017](#): (1) skin care regimen consisting of a moisturising body wash containing Shea butter and glycerin used daily and a moisturising leave-on hydrophilic water-in-oil emulsion lotion, and (2) skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea

[Hopp 1974](#): (1) lotion, (2) water soak, (3) water soak + lotion, (4) oil soak, (5) oil soak + lotion

[Shishido 2017](#): a hot towel used for 10 seconds after a usual care bed bath

**Comparison:** control (no intervention or standard care)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Hygiene + emollient interventions				
Frequency of skin damage (as recorded by clinicians according to STAR Skin Tear Classification) Outcome measured during 6 months	10.57 skin tears per month per 1000 occupied bed-days	5.76 skin tears per month per 1000 occupied bed-days	-	984 (1 study)	Very low <sup>a</sup>	Difference between groups: P = 0.004  This outcome was measured in <a href="#">Carville 2014</a>
Side effects from intervention (as and when observed) Outcome measured up to day 56 ± 4	Three undesirable effects were recorded in intervention group 1 (itch, redness, irritation) and 1 in intervention group 2 (mild skin dryness). No events in the control group		-	133 (1 study)	Very low <sup>b</sup>	This outcome was measured in <a href="#">Hahnel 2017</a>



<p>Transepidermal water loss (TEWL)</p> <p>Measured using temperature-adjusted g/m<sup>2</sup>/h with the Tewameter TM 300 (Courage + Khazaka, Cologne, Germany)</p> <p><b>Hahnel 2017:</b> measured at 56 ± 4 days</p> <p><b>Shishido 2017:</b> measured 15 minutes after wiping the skin with a dry towel for 1 second, and at same time point for comparator group (T5)</p>	<p>See comment    See comment</p>	<p>-</p>	<p>147 or 148 (2 studies)</p>	<p>Low<sup>c</sup></p>	<p>In <b>Hahnel 2017</b> at 56 ± 4 days, no clear difference between intervention 1 vs usual care (mid-volar forearm MD -2.70, 95% CI -7.67 to 2.27; and lower leg MD 0.10, 95% CI -3.55 to 3.76; and intervention 2 vs usual care (mid-volar forearm MD 0.70, 95% CI -5.81 to 7.21; and lower leg MD 0.00, 95% CI -3.62 to 3.62). There was no significant difference in TEWL between the 3 groups (mid-volar forearm P = 0.267, lower leg P = 0.773)</p> <p>In <b>Shishido 2017</b> at T5, the mean (SD) in the bed bath plus hot towel group (n = 21) was 8.6 g/m<sup>2</sup>/h (3.2) compared with 8.9 g/m<sup>2</sup>/h (4.1) in the bed bath only group (n = 21). The mean difference between groups was -0.30 g/m<sup>2</sup>/h (95% CI -2.52 to 1.92)</p>
<p>Stratum corneum hydration (SCH) (at baseline and day 56 ± 4)</p> <p><b>Hahnel 2017:</b> measured at 56 ± 4 days in mid-volar arm and lower leg in arbitrary units from 0 (no water) to 120 (on water) using the Corneometer CM 825</p> <p><b>Gillis 2016:</b> measured at 12 weeks using MoistureMeter SC with skin hydration scores reported in arbitrary units</p> <p><b>Shishido 2017:</b> measured immediately after wiping the skin 3 times (T3), immediately after wiping the skin with a dry towel (T4) and 15 minutes after T4 (T5), using a corneometer CM 825. Reference values were &gt; 50 arbitrary units for enough moisture, 35 to 50 arbitrary units for dry, and &lt; 35 arbitrary units for very dry</p>	<p>See comment    See comment</p>	<p>-</p>	<p>266 (3 studies)</p>	<p>Very low<sup>d</sup></p>	<p>In <b>Hahnel 2017</b>, no clear difference was found when either intervention was compared to usual care: intervention 1 vs usual care (mid-volar forearm MD 0.90, 95% CI -2.76 to 4.56; 74 participants; and lower leg MD 3.50, 95% CI -0.65 to 7.65); and intervention 2 vs usual care (mid-volar forearm MD 1.00, 95% CI -3.03 to 5.03; 75 participants; and lower leg MD -1.10, 95% CI -5.13 to 2.93)</p> <p>In <b>Gillis 2016</b>, the study authors reported no statistically significant difference between control and intervention groups (P = 0.412). The arbitrary units in the intervention group compared to the control group were 5.22, 1.84, and 16.33 units higher for the leg, hand, and cheek, respectively. However, data were presented only in a graph, and it is unclear if the data provided were means and standard errors, or other measures</p>

In [Shishido 2017](#) at T3, the mean stratum corneum hydration in the bed bath plus hot towel application was 104.4 (SD 8.1) vs 94.9 (15.7) in the bed bath only group, showing significantly more stratum corneum hydration in the hot towel group: MD 9.50, 95% CI 1.94 to 17.06. At T4, the mean stratum corneum hydration in the bed bath plus hot towel application was 67.3 (SD 11.1) vs 59.7 (12.4) in the bed bath only group, showing significantly more stratum corneum hydration in the hot towel group: MD 7.60, 95% CI 0.48 to 14.72. However at T5, the mean difference between groups was no longer statistically significant: MD -0.40, 95% CI -4.76 to 3.96; mean 40.2 (SD 8.0) in the hot towel group vs 40.6 (6.3) in the bed bath only group

Erythema	See comment	See comment	-	-	-		This outcome was not measured in any of the included studies
Clinical score of dryness <a href="#">Hahnel 2017</a> : measured at day 56 ± 4 using the Overall Dry Skin Score <a href="#">Boccanfuso 1978</a> : measured after 10 applications using a non-validated General Foot Condition Questionnaire including a Dryness Scale (1 = oily; 2 = normal, appears hydrated; 3 = dry-rough texture, lack of moisture; 4 = scaly + 1 - scant, white scales; 5 = scaly + 2 - few yellow, oily scales; 6 = scaly + 3 - moderate to many white scales; 7 = scaly + 4 - many thick yellow scales) <a href="#">Hopp 1974</a> : measured at 8 days using a non-validated xerosis severity score	See comment	See comment	-	245 (3 studies)	Low <sup>e</sup>		<a href="#">Hahnel 2017</a> : intervention 1 had less dryness in right forearm (MD -0.60, 95% CI -1.02 to -0.18), left lower leg (MD -0.60, 95% CI -1.08 to -0.12), and trunk (MD -0.40, 95% CI -0.70 to -0.10) compared to usual care, but result was not significant in left forearm (MD -0.30, 95% CI -0.94 to 0.34) or right lower leg (MD -0.20, 95% CI -0.87 to 0.47). Intervention 2 had less dryness in left lower leg (MD -0.50, 95% CI -0.96 to -0.04), right forearm (MD -0.60, 95% CI -1.05 to -0.15), left forearm (MD -0.60, 95% CI -1.05 to -0.15), and trunk (MD -0.30, 95% CI -0.60 to -0.00) compared to usual care; no clear difference in right lower leg (MD -0.40, 95% CI -0.86 to 0.06). Intervention groups were significantly better than control groups in all body areas (right forearm P =



0.006, left forearm P = 0.011, trunk P = 0.013) except lower legs (right lower leg P = 0.121, left lower leg P = 0.073)

In [Boccanfuso 1978](#), skin flaking was reduced in both groups, and significant improvement was noted in intervention compared with control group after 10 applications (P < 0.05)

In [Hopp 1974](#), all intervention groups showed statistically significant improvement in dry skin compared with the control group at 8 days. Interventions of water + lotion (dryness score 1.3656), oil soak + lotion (dryness score 1.1181), lotion (dryness score 1.0054), and oil soak (dryness score 0.88388) were all significantly effective in reducing skin dryness compared with control (dryness score = 0.20149) (P < 0.0001)

Clinical score of itch	See comment	See comment	-	-	-		This outcome was not measured in any of the included studies

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; MD: mean difference; SD: standard deviation.

#### GRADE Working Group grades of evidence.

**High quality:** we are very confident that the true effect lies close to that of the estimate of the effect.

**Moderate quality:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

**Low quality:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

**Very low quality:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

<sup>a</sup>Downgraded by three levels to very low quality: two levels due to high risk of attrition bias, performance bias, and detection bias, and unclear risk of selection bias; and one further level due to imprecision, as the outcome was assessed by only one trial.

<sup>b</sup>Downgraded by three levels: one level due to high risk of attrition and detection bias; and two levels due to imprecision, as this outcome was assessed in only one study and the event rate was low.

<sup>c</sup>Downgraded by two levels: one level due to high risk of performance, detection, and attrition bias; and one level due to imprecision, as this outcome was assessed in two studies, which could not be pooled.

<sup>d</sup>Downgraded by three levels: two levels due to high risk of performance, detection, and attrition bias; and one level due to imprecision, as this outcome was assessed in only three studies and data could not be pooled.

<sup>e</sup>Downgraded by two levels: one level due to high risk of attrition bias; and one level due to high risk of performance bias.

## BACKGROUND

Please see [Table 1](#) for a glossary of terms.

### Description of the condition

Globally, the population is ageing, and this is a particular issue in the western world ([United Nations 2017](#)). The numbers of older people living in care settings and occupying hospital inpatient beds are 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 ([Associate Parliamentary Group on Skin 2000](#); [Fore 2006](#)). The skin, as the largest organ system in the human body ([Swann 2010](#)), 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 health, as through temperature regulation and protection of deeper tissues from ultraviolet radiation and pathogenic organisms ([Kottner 2015](#)).

The term 'skin integrity' refers to the skin as a sound and intact structure. 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](#)). The skin has an acidic surface pH, which is important for maintaining skin integrity thorough microflora regulation and physiological processes ([Lambers 2006](#)).

As skin ages, it undergoes many intrinsic and extrinsic degenerative changes ([Farage 2007](#); [Ronda 2002](#)). Intrinsic skin ageing is due to largely unpreventable biological changes ([Lawton 2007](#)). Please see [Table 2](#) for a list of examples of intrinsic skin changes and their effects on the skin. Additional factors, such as damage caused by exposure of the skin to the environment ([Cowardell 2011](#)), including ultraviolet light, cause extrinsic ageing. Other influences on the skin health of older people 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. The cumulative effect of the ageing process is that the skin becomes a less effective barrier, risk of infection is increases, and wound healing is delayed. These changes make the skin significantly more vulnerable to damage" ([Cowardell 2015](#)).

It is generally agreed that xerosis (skin dryness), fissures (cracks), and pruritus (itching) are common among older people ([Cowardell 2018](#)). However, these conditions often go untreated ([Kirkup 2008](#)). Although such conditions may be considered 'minor', they can have a significant impact on the individual and on healthcare systems. Skin damage can have a devastating effect on the older person and can cause distress for both them and their carers. It is clinically challenging and has the potential to cause significant morbidity ([Farage 2007](#)), leading to diminished quality of life. Xerosis brings with it increased risk of other signs and symptoms including discomfort, itch, infection, and skin lesions ([Cole 2004](#); [Hunter 2003](#)). Older 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](#)). Skin damage can lead to increased length of stay in hospital and higher levels of dependence in residential homes, and it can be a challenge for acute and community care ([Gardiner 2008](#)). Pruritus caused by

irritants creates the desire to scratch, which then causes further damage to the skin in a vicious, escalating cycle (the itch-scratch cycle) ([Cork 1997](#)).

Evidence on the prevalence of skin problems among older people is limited. Few epidemiological surveys have been undertaken, and each has incorporated different methods 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 generally dated; however there is a dearth of up-to-date research. In an attempt to provide clinically relevant data about skin disease and skin care needs among older people, [Beauregard 1987](#) examined the skin of 68 non-institutionalised volunteers aged 50 to 91 and questioned them. This examination 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 over 64 years of age 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](#)). In a more recent survey of 1116 community-dwelling older people, 16.5% (n = 183) reported skin concerns. Among this group, the most common concerns were dry skin (80.7%; n = 146) and itching (56.9%; n = 103). There was a significant association between dry skin and itch ( $\chi^2 (1) = 6.9$ ;  $P < 0.05$ ; [Cowardell 2018](#)).

It is estimated that xerosis affects 59% to 85% of older people ([Beauregard 1987](#)). The estimated prevalence of dry skin among 1710 older people in hospital and home care settings, based on the Overall Dry Skin Score ([Serup 1995](#)), was 48.8% ([Lichterfeld 2016](#)). A systematic review of primary incidence or prevalence studies or secondary data analyses of skin conditions or diseases among older people predominantly in care settings suggests rates of xerosis ranging from 5.4% to 85.5%; review authors note methodological weaknesses that may account for this wide range of prevalence ([Hahnel 2016](#)).

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 chronic diseases that reduce the skin's ability to repair damage, such as diabetes and cardiovascular disease; and the numerous psychosocial factors that come with increasing age and that increase the likelihood of skin breakdown ([Lichterfeld-Kottner 2019](#)). Although it is commonly assumed that older people are less susceptible to the psychosocial impact of skin problems, [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](#)).

Personal hygiene is one of many elements that contribute to maintaining skin integrity. Skin cleanliness and prevention of skin breakdown are essential ([Voegeli 2008a](#)). Enhancement of comfort and well-being, a notion that [Ong 1998](#) describes as the 'look good – feel good' factor, is of equal importance.

A majority of people regularly wash or bathe independently ([Evans 2004](#)). However, older people may experience greater difficulty in completing their usual personal hygiene practices without some assistance. Skin care is "one of the core elements of care in all fields of nursing" ([Cowardell 2015](#)), and personal hygiene is an important

part of this. Older people may prefer not to seek help with personal hygiene, and it is important that any assistance given maintains dignity (ANA 2001; DH 2006). The focus should be on educating older people about optimal but achievable skin care and promoting independence.

It is argued that existing personal hygiene practices are largely based on 'tried and tested practice' (Lentz 2003), as the evidence base is poorly developed (Hodgkinson 2007; Holloway 2005), and this situation has changed little over time. Washing and moisturising routines can vary substantially in hospital and care homes depending on personal preferences of both residents and carers, level of independence with personal care, and availability of wash products.

In a systematic review of evidence-based skin care for older people, Kottner 2013 concluded that little is known about the relative benefits of different cleansing and moisturising regimens, and this message is reinforced in a critical discussion of nursing practice and research in this important area (Kottner 2016). Lentz 2003 suggests that existing practices may be detrimental to skin health. In an experimental cohort study of washing with soap and water and towel drying, Voegeli 2008b found that this process causes disruption to skin barrier function. There are guidelines for providing personal care with varying degrees of underpinning evidence (e.g. Dougherty 2008; Downey 2008). Some consensus has been reached on recommended practices for providing personal hygiene care; however, this is largely based on clinical experience.

It is possible that the nursing care currently provided in hospitals and residential homes may damage the skin of ageing patients because of well-meant but too frequent washing. It is essential that there is a balance between maintaining health and well-being by meeting personal hygiene needs and not over-cleansing the skin, 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.

Terminology related to washing and moisturising practices in maintaining the skin health of older people can be ambiguous. Kottner 2016 states that there is a need for a standardised language of skin care and skin care products that can be used when clinical research is planned and undertaken. We have offered a glossary of terms (Table 1), and for clarity, we have given examples of included interventions and primary outcome measures.

## Description of the intervention

Numerous skin cleansing and emollient products are available, although few have been developed specifically for older people. In residential care and hospital settings, people are likely to wash or be helped to wash at least daily, and sometimes more often according to their condition.

### Cleansers

Skin cleansers are available globally in various forms, including bars, liquids, gels, and creams, to be used in combination with water. Some pre-packaged specialist bed baths/wet wipes contain pre-moistened cloths with evaporating no-rinse cleansers and emollients (Massa 2010). The purpose of skin cleansing is to remove dirt, soil, and bacteria from the skin. The type of surfactant used, natural or synthetic (the key cleansing ingredient), has an effect on the mildness or otherwise of the product (Abbas 2004).

Natural surfactants (soaps) are the most common cleansing agents. Alternatives to soap-based cleansers include synthetic surfactant-based syndet (synthetic detergent) products (Abbas 2004), along with emollient-rich bath additives and shower preparations.

Surfactants in all cleansers can cause immediate post-wash tightness (Kawai 1984), dryness (Imokawa 1989), and barrier damage, irritation, itch, and erythema (Wilhelm 1993). Soaps and detergents can increase the pH of the stratum corneum, which enhances protease activity and inhibits synthesis of lipid lamellae. Surfactant residues may form an irritant reservoir on the skin, even after rinsing (Loden 2003).

Soap-based products are more damaging to the skin than syndets (Barel 2001). Use of harsh cleansing products can lead to breakdown of skin barrier function (Cork 2009). This potential skin barrier disruption is a particular issue for older people, who are likely to already have dry and fragile skin.

Many cleansers are available to the public without the need for a healthcare consultation. Products should have minimal adverse effects and should be acceptable to the person to promote concordance (Cowdell 2010).

### Drying

After cleansing with water and a cleansing agent, drying of the skin is essential and is generally achieved by towel drying using 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 also risk of discomfort or damage, for example, from abrasion (Voegeli 2010).

Bed bath wipes obviate the need for drying, relying instead on evaporation (Massa 2010).

### Leave-on emollients

Leave-on emollients are skin moisturisers that leave a barrier of artificial lipids (such as petrolatum or mineral oil) or natural fats (such as Shea butter) on the skin surface, thus trapping water in the stratum corneum (SC) (reducing transepidermal water loss) (Danby 2011). They are linked with reduced skin dryness and pruritus and improved skin barrier function (Darsow 2009). The consistency and occlusive properties of the emollient depend on the levels of lipid or oil and water; this underpins the categorisation of emollients as ointments, creams, or lotions (Djokic-Gallagher 2012), and, more recently, as gels and aerosol preparations. Ointments have the least amount of water and the most lipids and therefore exhibit greater skin occlusion (Peacock 2016). Creams contain similar amounts of water and oil and are more easily spread across the skin compared with ointments, making them more cosmetically acceptable (Peacock 2016). To emulsify the lipid and aqueous phases of an emollient, surfactants are required (Lodén 2003a). 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 actions (Betzuege 2005).

A recent Cochrane Review on the use of emollients in eczema concludes that although most products show some positive effect, there is currently no reliable evidence suggesting that one moisturiser is more effective than another (van Zuuren 2017). Not only do emollients reduce the level of dry skin, they are now thought to be a promising intervention for prevention of skin conditions such as atopic dermatitis and asteatotic eczema, which are due to very dry skin (Simpson 2014). The role of emollient wash products in treatment and prevention of dry skin conditions is still unclear because clinical evidence is sparse (Tarr 2009).

Many emollients are available to the public without the need for a healthcare consultation. The ideal emollient intervention is one that maintains or promotes skin integrity and comfort. This intervention should have minimal adverse effects, and products should be acceptable to the person using them to promote concordance (Cowardell 2010).

### Why it is important to do this review

An Associate Parliamentary Group on Skin (APGS) report highlighted that older people suffer from lack of sensitivity to their skin care needs and related problems (Associate Parliamentary Group on Skin 2000). It also found that training was lacking for healthcare professionals who seek to manage the skin care needs of older people, and that preventive interventions were inadequate. Although it was published 18 years ago, the APGS report still has resonance. Healthcare professionals are ideally placed to recognise skin problems when helping with personal hygiene needs or performing treatments (Lawton 2010). To provide optimal care, they should have an understanding of the skin changes associated with age and common conditions affecting the older person. They also need to be able to assess the older person's ability (physical and mental) to manage and treat his/her skin effectively and independently, and when to intervene (Penzer 2001). "There is an increasing emphasis on timely skin assessments and preventative care that supports maintenance or improvement in skin integrity. With this greater emphasis on keeping the patients skin clean, dry and well hydrated, there is now more than ever the need to understand which products should be used for personal hygiene and which products can be used to prevent further skin damage in this patient group" (Nursing in Practice 2014).

Maintaining skin hygiene and preserving or improving skin barrier function are essential for ensuring the health and well-being of older people (Pegram 2007), particularly those in care environments such as hospitals and residential settings. This is a topic of substantial concern for those people affected, their families, and healthcare providers, with significant implications for healthcare systems worldwide. Much research has focused on secondary and tertiary prevention in skin care, such as management of incontinence-associated dermatitis and pressure ulcer prevention. However, few studies have addressed prevention - 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 was conducted to identify gaps in current knowledge, and thus to inform the future research agenda, leading to rigorously developed and contextually appropriate guidelines that take into account effectiveness and acceptability to older people and their healthcare practitioners (Gardiner 2008); and to provide a firm foundation for future healthcare practice. Cost-effectiveness is an important issue but is beyond the scope of this review.

Plans for this review were published in the protocol 'Hygiene and emollient interventions for maintaining skin integrity in older people in hospital and residential care settings' (Cowardell 2014).

## 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 considered all randomised controlled trials (RCTs) of hygiene and emollient interventions. We excluded quasi-randomised trials.

#### Types of participants

Men and women aged  $\geq 60$  years in hospital or residential care settings.

#### Types of interventions

We identified 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 (e.g. immersion bath versus bed bath versus strip wash versus shower); frequency of hygiene practices (e.g. daily, weekly); and types and dosages (e.g. water only versus soap and water versus other skin cleansers).
- Emollient regimens, including the following.
  - \* Method of application (e.g. bath or shower products or leave-on emollients); types and dosages (e.g. lotions, creams, ointments, number of grams per application); and frequency of use (e.g. once daily, twice daily, more frequently).

The following comparisons were conducted.

- 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 were of interest to us in any combination as measured by clinician, participant, carer, or other outcome observer. We accepted outcome measures however measured. We have indicated reliability and validity of measures (where relevant) in Table 3 ("Summary of intervention characteristics").



### Primary outcomes

- Frequency of skin damage (e.g. complete loss of integrity such as tears or ulcerations, partial loss of integrity such as fissuring)
- Side effects of intervention, frequency of cutaneous reaction (irritant or allergic) to intervention (emollient or cleanser use)

### Secondary outcomes

- Transepidermal water loss (TEWL)
- Stratum corneum hydration (SCH)
- Erythema (redness) (subjective assessment of erythema as performed clinically, objective assessment as measured using a chroma metre)
- Clinical score of dryness
- Clinical score of itch

### Tertiary outcomes

- Corneosurfametry (CSM)
- Skin surface pH measured with a flat pH electrode
- Resident microbes (microbiome analysis)
- Types and concentrations of SC lipids

### Search methods for identification of studies

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

#### Electronic searches

We searched the following databases up to 23 January 2019.

- Cochrane Skin Specialised Register, using the search strategy presented in [Appendix 1](#).
- Cochrane Central Register of Controlled Trials (CENTRAL; 2018, Issue 12), in the Cochrane Library, using the strategy in [Appendix 2](#).
- MEDLINE via Ovid (from 1946), using the strategy in [Appendix 3](#).
- Embase via Ovid (from 1974), using the strategy in [Appendix 4](#).
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCO (from 1981), using the strategy in [Appendix 5](#).

#### Searching other resources

##### Trials registers

We searched the following trials registers up to 23 January 2019.

- International Standard Randomized Controlled Trials Number (ISRCTN) registry ([www.isrctn.com](http://www.isrctn.com)), using the search terms in [Appendix 6](#).
- ClinicalTrials.gov ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)), using the terms in [Appendix 7](#).
- Australian New Zealand Clinical Trials Registry ([www.anzctr.org.au](http://www.anzctr.org.au)), using the terms in [Appendix 8](#).
- World Health Organization International Clinical Trials Registry platform (ICTRP) ([www.who.int/trialsearch](http://www.who.int/trialsearch)), using the terms in [Appendix 9](#).
- EU Clinical Trials Register ([www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)), using the terms in [Appendix 10](#).

### References from published studies

We checked the bibliographies of included studies for further references to relevant trials.

#### Adverse effects

We did not perform a separate search for adverse effects of the target interventions. However, we examined data on identified adverse effects from the included studies.

### Data collection and analysis

We used standard methodological procedures as expected by Cochrane. Please note that some parts of the methods section of this review use text that was originally published in other Cochrane Reviews and protocols, predominantly [El-Gohary 2014](#) and [Ersner 2014](#).

#### Selection of studies

We included only RCTs. Two review authors independently checked titles and abstracts identified through the searches (FC and YJ or JD). If it was clear that the study did not refer to an RCT on hygiene and emollient practices for older people in hospital or residential care settings, we excluded it. If unclear, we obtained the full text of the study for independent assessment by two review authors (FC and YJ or JD). The same two review authors decided by consensus which trials fulfilled the inclusion criteria. In the event of disagreement, we planned to involve a third review author to achieve resolution. We listed in the [Characteristics of excluded studies](#) tables of the review any studies that we thought at first met the eligibility criteria but then excluded.

#### Data extraction and management

Two review authors (FC and YJ or JD) independently extracted data from the included studies using a data collection form, which was subjected to pilot testing before use. The two review authors resolved by discussion any differences that arose during data extraction. In the event of continued disagreement, we planned to involve a third review author to achieve resolution. Data collected included details about participants, design of the study, assessment of risk of bias, interventions, outcomes, and results.

Following recommendations by Cochrane after publication of the protocol, we intended to use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) profiler (GRADEpro) to assess the quality of evidence for each review outcome ([Balslem 2011](#); [Guyatt 2011](#)). The following five factors were taken into consideration: study limitations (risk of bias), inconsistency of results, indirectness of evidence, imprecision, and publication bias. The quality of evidence could be graded from high to moderate, low, or very low quality.

#### Assessment of risk of bias in included studies

Two review authors (JD and YJ) independently assessed all included studies for risk of bias. We did this using the risk assessment tool provided in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). For each study, we assessed risk of bias using the domains listed below. We assessed each domain as having 'low' (low risk of bias), 'high' (high risk of bias), or 'unclear' (unclear risk of bias) risk. When no information was available to make a judgement, we explicitly noted this. When we lacked information, we contacted the corresponding author

when possible. Due to the age of two of the papers (Boccanfuso 1978; Hopp 1974), we were unable to contact study authors for clarification, hence in these papers we were obliged to report 'unclear risk' more frequently than we would have preferred. We resolved disagreements by discussion involving a third review author when required. We have included details of bias in a 'Risk of bias' table for each study included in the review. We looked at the following domains.

### **Selection bias**

#### **Sequence generation**

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

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

#### **Allocation concealment**

We described how allocation concealment was achieved and assessed whether allocation may have been anticipated before or during participant recruitment.

For example, we considered risk of bias to be low if randomisation was carried out independently (Jüni 2001), and we considered risk to be high if allocations were given from a list on a sheet of paper on a trial investigator's desk.

### **Performance bias**

#### **Blinding of participants and personnel**

We described for each included study all methods used to ensure blinding of participants and researchers. For example, if an included study compared a control emollient with an intervention emollient and reported that blinding was achieved through use of identical packaging, we considered the risk of performance bias as low. If blinding had not happened, we assessed whether this may have introduced bias.

#### **Detection bias**

##### **Blinding of outcome assessment**

We made a judgement about whether outcome assessors in trials were blinded to the intervention. We gave an included study a low risk of bias judgement if a clear description of measures taken to prevent contact between staff delivering the intervention or control treatment and those assessing outcomes and analysing trial data was given. On the other hand, if we found evidence of contact between these staff groups and this lack of blinding was likely to affect the outcome measurement process, we gave a high risk of bias judgement.

#### **Attrition bias**

##### **Incomplete outcome data**

We scrutinised studies for incomplete outcome data. For each study, we provided the number of trial participants in each intervention group and compared this with the overall number of randomised participants. We stated whether any withdrawn

participants or excluded data had been reported. When applicable, we gave the reasons for this. We used guidance from Section 8.5 of Higgins 2011 to classify studies. For example, if outcome data were missing for administrative reasons, this was unlikely to be related to unobserved outcome measurements, and we made a low risk of bias judgement.

### **Reporting bias**

#### **Selective reporting**

We examined each study for the possibility of selective reporting. As in the previous subsection, we used guidance from Section 8.5 of Higgins 2011 to classify studies. For example, if we found evidence that all outcomes the study authors planned to measure had been reported, we made a low risk of bias judgement. However, if some planned outcomes had been reported incompletely or not at all, we made a high risk of bias judgement.

#### **Additional sources of bias**

We examined all papers for additional sources of bias over those listed above.

#### **Measures of treatment effect**

We planned to report means and standard deviations for continuous outcome measures and percentages of successful outcomes for dichotomous outcome measures. If we could directly combine the studies included in the review, we planned to use the meta-analysis techniques discussed in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We intended to use odds ratios as measures of treatment effect for dichotomous outcome measures. We intended 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 included a within-patient trial (e.g. different interventions were used for different parts of the body), we planned to use methods that took within-patient pairing into account. In the event of the inclusion of any cross-over trials in the review, if possible, we planned to obtain measures of treatment effect based on a paired t-test. We did not plan to combine these results with results from parallel-group trials.

We did not plan to combine results from cluster-randomised studies with results from parallel-group trials in case such studies differ in other ways apart from study design. In the case of cluster-randomised trials, we intended to extract the direct estimate of the required effect measure (e.g. odds ratio with confidence intervals) and to conduct multi-level modelling to allow individual-level analysis while accounting for clustering of data (Higgins 2011).

If studies with multiple intervention arms were included, we would combine the groups when appropriate, or we would include the different comparisons in separate meta-analyses to avoid double-counting.

#### **Dealing with missing data**

In the event of missing data being substantial enough for studies to be classified as having high risk of bias or the need to clarify particular issues, we contacted the authors of the studies in

question. If necessary, we planned to perform a sensitivity analysis to assess the impact on the overall treatment effect when our attempts to obtain further details from the original study authors were unsuccessful. It would have been necessary to conduct a meta-analysis twice, first with all studies included using an available case analysis, and then with studies with higher levels of potential bias including attrition bias arising from missing data excluded.

### Assessment of heterogeneity

Assuming outcome measures from included studies were potentially comparable in the first place (please see the [Data synthesis](#) section), we planned to test for heterogeneity of the effect of the intervention 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 intended to assess whether this was due to a single 'outlier' study. If this was the case, we would have performed and reported meta-analyses both with and without this study. If there were no obvious outlying studies, we would have tried to establish the reasons for heterogeneity and come to a decision on the viability of a meta-analysis.

### Assessment of reporting biases

We intended to assess publication bias using funnel plots if we had included at least 10 studies (following the recommendations in Chapter 10 of [Higgins 2011](#)), and if a meta-analysis had been feasible. We were mindful of the caveats associated with the use of funnel plots. If asymmetry had been detected, we would have considered publication bias as a potential cause.

### Data synthesis

We first assessed whether each of our outcomes of interest was measured in a large enough subset of studies to allow for a meta-analysis. We also assessed whether the intervention and control groups in each of the studies and the research designs were consistent enough for us to synthesise a global 'hygiene or emollient practice versus control' effect. If there had not been too much diversity, we would then have compared outcome measures across studies for each outcome of interest. We planned to use the meta-analysis techniques in Chapter 9 of [Higgins 2011](#) for combining outcome measures on different scales, provided there was no evidence that some study populations were genuinely more variable than others. We would then test for heterogeneity of the intervention effect as described in the [Assessment of heterogeneity](#) section. If substantial diversity or (statistical) heterogeneity was identified between studies, or if the number of included studies was very small, we intended to not perform a meta-analysis but instead present a narrative analysis that included details of study results, trial interventions, and study design.

If studies were pooled, we planned to use a fixed-effect meta-analysis. We did not plan to pool study data if the  $I^2$  statistic was greater than 50% and this was not due to a single 'outlier' study (please see the [Assessment of heterogeneity](#) section).

When results were estimated for individual studies with small numbers of outcomes (< 10 in total), or when the total sample size was less than 30 participants, we intended to report the proportion of dichotomous outcomes in each treatment group together with a P value from Fisher's exact test.

We conducted a narrative synthesis, as quantitative synthesis of the included studies would not be appropriate or meaningful due to heterogeneity in intervention ingredients, body areas treated, and outcome measures. We used two approaches to narrative synthesis.

- Structured description of each of the studies.
- Tabulation of results to identify patterns across studies ([Table 3](#)).

### Subgroup analysis and investigation of heterogeneity

As reported in the [Assessment of heterogeneity](#) section, we planned to assess statistical heterogeneity using the  $I^2$  statistic. We decided to consider the possibility of subgroup analyses involving study-level covariates only if more than 10 studies were included.

### Sensitivity analysis

In the event that we had decided to use a meta-analysis, and that some studies were found to have higher levels of potential bias when the 'Risk of bias' checklist was applied, we would have performed a sensitivity analysis. This would have involved conducting a meta-analysis twice - first with all studies included, and then with omission of studies with high risk of bias for any of the five assessed domains and assessment of how much this changes the overall estimate of intervention effect.

### Summary of findings and assessment of the certainty of the evidence

We summarised the review results in a 'Summary of findings' table, comparing hygiene and emollient regimens to a control (either no intervention or standard care). We included our primary outcomes (frequency of skin damage and side effects from the intervention) as well as our secondary outcomes (transepidermal water loss, stratum corneum hydration, erythema, clinical score of dryness, and clinical score of itch).

## RESULTS

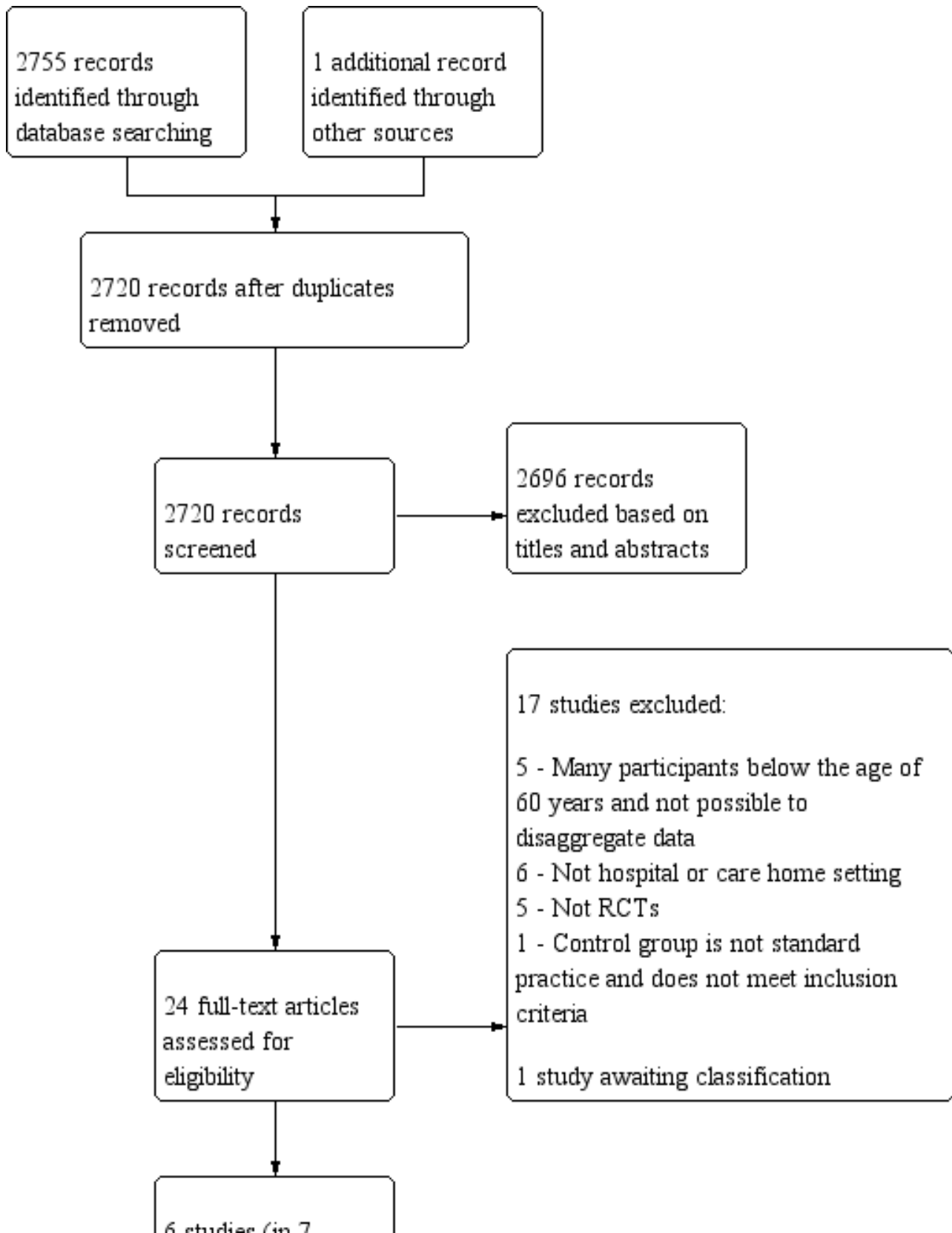
### Description of studies

#### Results of the search

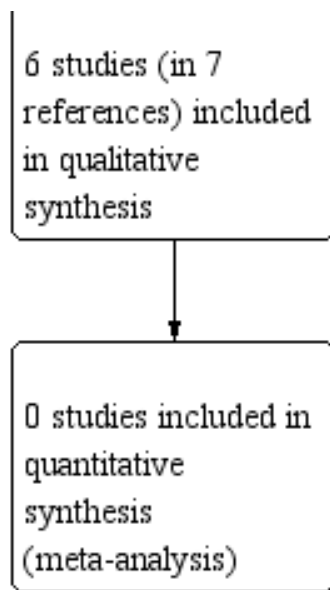
Through searches of databases and trials registers (see [Electronic searches](#)), we retrieved 2755 records. We retrieved one record from other sources, for a total of 2756. We excluded 2696 records based on title and abstract review. We obtained the full text of the remaining 24 records and information about the study awaiting classification. We excluded 17 studies because they did not meet our inclusion criteria. We included six studies from seven references (see [Characteristics of included studies](#)). For a further description of our screening process, see the study flow diagram ([Figure 1](#)).



**Figure 1. Study flow diagram.**



**Figure 1. (Continued)**



**Included studies**

Narrative synthesis based on a structured description of each study is provided below, and data are tabulated in Table 3. We included in this review six RCTs, with 1598 participants. These studies investigated hygiene practices or emollient practices, or both, for older people in residential care settings. We noted heterogeneity in intervention ingredients, comparison groups, body areas treated, and outcome measures; therefore, meta-analysis was not possible, and we have presented a narrative review.

Support from an industry statistician was reported by Boccanfuso 1978. Carville 2014 reported funding from the Wound Innovation CRC, and Hahnel 2017 reported funding from Galderma Pharma and the Clinical Research Center for Hair and Skin Science, Department of Dermatology and Allergy, Charité - Universitätsmedizin Berlin; both studies report that study conduct was independent of funding. Funding from Curando vzw covered the cost of the MoistureMeter SC and writing of the manuscript in Gillis 2016. Funding sources were not reported for Hopp 1974 or Shishido 2017.

**Study design**

One study was a parallel, individually randomised, three-arm RCT (Hahnel 2017), and two studies used randomised clusters (Carville 2014; Gillis 2016). Two studies randomised parts of the body (legs and feet) and were classified as within-participant studies (Boccanfuso 1978; Hopp 1974). One study used a cross-over design (Shishido 2017).

**Participants**

All interventions were delivered in care home settings. The population samples studied were taken from the following: long-term-care facilities in Germany whose residents had a mean age of 83.8 years (Hahnel 2017), two long-term healthcare facilities in Japan whose residents had a mean age of 84.8 years (Shishido 2017), six wards within two nursing homes in Flanders (Northern Belgium) with residents aged 80+ years (Gillis 2016), an aged care facility in Australia whose residents were predominantly over 80

years of age (Carville 2014), a US home for the elderly (aged 65 to 100 years) (Boccanfuso 1978), and a US nursing home facility with residents over 60 years of age (Hopp 1974). In two studies, the gender of participants was not specified (Boccanfuso 1978; Hopp 1974); in the other studies, 65% (Carville 2014; Hahnel 2017), 68% (Gillis 2016), and 95% of participants were female (Shishido 2017). Two of the six studies were conducted in relatively hot climates, namely, Western Australia and Arizona, USA, respectively (Boccanfuso 1978; Carville 2014). One study focused attention on the importance of considering the relative humidity of the ambient environment (Boccanfuso 1978), and one focused on temperature and humidity (Shishido 2017). Two studies included only people with diagnosed dry skin (Boccanfuso 1978; Hahnel 2017).

**Interventions and comparators**

Each study used different intervention types with products including many different ingredients.

- Hahnel 2017 compared (1) a moisturising body wash containing Shea butter and glycerin with a moisturising leave-on, hydrophilic, water-in-oil emulsion lotion (body lotion), and (2) a moisturising body wash containing glycerin alone with a water-in-oil emulsion (body lotion) containing emollients and 4% urea versus care as usual (continuing with an individual's usual personal hygiene and care products).
- Shishido 2017 compared a hot towel applied for 10 seconds after a usual care bed bath versus a usual care bed bath.
- Gillis 2016 compared usual care (a traditional bed bath) versus usual care using 'wash gloves' containing aqua, propylene glycol, coco-glucoside, phenoxyethanol, parfum, benzoic acid, polyaminopropyl biguanide, octyldodecanol, aloe barbadensis, glycine soja oil, dehydroacetic acid, sodium lauroamphoacetate, Calendula officinalis extract, Tilia cordata extract, Melissa officinalis extract, Hamamelis virginiana extract, Echinacea purpurea extract, Chamomilla recutita extract, Centella asiatica extract, aloe barbadensis gel, or tocopherol.

- [Carville 2014](#) used a commercially available, pH-neutral, perfume-free moisturising lotion plus usual care versus usual care (ad hoc or no standardised skin-moisturising regimen).
- [Boccanfuso 1978](#) compared a moisturising soap containing a 'special protein', a lanolin derivative (an emulsifier, i.e. a fat removal chemical), and glycerin (a humectant with emollient properties) versus a soap bar without these ingredients.
- [Hopp 1974](#) tested five combinations of water soak, oil soak, and lotion and compared the following groups with Group A control (no intervention), Group B lotion, Group C water soak, Group D water soak and lotion, Group E oil soak, and Group F oil soak and lotion. Oil and lotion contained "a combination of dewaxed, oil-soluble, keratin-moisturising fraction of lanolin, mineral oil, and non-ionic emulsifiers".

The frequency of intervention varied from once-daily use of wash products and twice-daily application of leave-on emollient ([Hahnel 2017](#)), to 10-second application of a heated towel ([Shishido 2017](#)), twice-daily application of lotion ([Carville 2014](#)), twice-daily washing ([Boccanfuso 1978](#)), and daily treatment ([Hopp 1974](#)). In [Gillis 2016](#), most of the residents had a shower or bath once a week (defined as frequent bathing).

The duration of intervention was five days ([Boccanfuso 1978](#)), 12 days ([Hopp 1974](#)), eight weeks ([Hahnel 2017](#)), 12 weeks ([Gillis 2016](#)), and six months ([Carville 2014](#)). In [Shishido 2017](#), the intervention was given once (hot towel applied for 10 seconds).

Body areas assessed were the hand, leg, and cheek ([Gillis 2016](#)); both arms and legs and trunk ([Hahnel 2017](#)); inner forearm ([Shishido 2017](#)); extremities ([Carville 2014](#)); lower legs ([Boccanfuso 1978](#)); and feet ([Hopp 1974](#)). [Hahnel 2017](#) trained nurses or participants (depending on their level of independence) to use the study products. In [Carville 2014](#), interventions were delivered by residents if they were able, and by staff following education. In [Gillis 2016](#), interventions were delivered by staff following education. It is not clear who delivered the intervention in one study ([Boccanfuso 1978](#)), and the range of interventions in [Hopp 1974](#) and the hot towel intervention in [Shishido 2017](#) were provided by a researcher.

## Outcome measures

### Primary outcome measures

#### Frequency of skin damage

One study (n = 1164) - [Carville 2014](#) - assessed frequency of skin tears using the STAR Skin Tear Classification ([Carville 2007](#)).

#### Side effects from intervention

Another study (N = 133) assessed side effects through observation ([Hahnel 2017](#)).

### Secondary outcome measures

#### Clinical score of dryness

Three of the six studies observed skin condition with reference to xerosis using different methods. [Hahnel 2017](#) employed the validated Overall Dry Skin Score ([Serup 1995](#)), [Boccanfuso 1978](#) used a visual scale from 0 to 5 with 0 = no flaking to 5 = crusting, and [Hopp 1974](#) used a 7-point scale ranging from oily to scaly +4 with many thick yellow scales. Two of the assessments of dry skin appear to have been developed specifically for individual studies,

and there is no evidence of validity ([Boccanfuso 1978](#); [Hopp 1974](#)); hence, these results should be taken with caution.

### Transepidermal water loss

This was measured by [Hahnel 2017](#) and [Shishido 2017](#) (using the Tewameter TM 300, Courage + Khazaka, Cologne, Germany).

### Stratum corneum hydration (SCH)

This was measured by [Gillis 2016](#), [Hahnel 2017](#), and [Shishido 2017](#). [Hahnel 2017](#) and [Shishido 2017](#) used the Corneometer CM 825 (Courage + Khazaka, Cologne, Germany), and [Gillis 2016](#) used the MoistureMeter SC (Delfin Technologies Ltd, Stamford, Connecticut, USA).

### Tertiary outcome measures

#### Skin surface pH

Only [Hahnel 2017](#) measured skin surface pH (using the Skin-pH-Meter1 PH 905, Courage + Khazaka).

Other skin-related outcomes included skin surface temperature using the Skin-Thermometer ST 500 (Courage + Khazaka, Cologne, Germany) ([Hahnel 2017](#)); Thermography R300 (NEC, Tokyo, Japan) ([Shishido 2017](#)); and a General Foot Condition Questionnaire, which assessed whether the skin was oily, normal, dry, or scaly (ranging from 1 to 4) for the dorsum and plantar surfaces of the foot for different areas such as toes, top, heel and toes, ball, and arch and heel, respectively ([Hopp 1974](#)).

### Excluded studies

Seventeen studies were excluded for the following reasons: many participants < 60 years of age and not possible to disaggregate data (5), not set in a hospital or residential care facility (6), not an RCT (5), and not a comparison of intervention versus no intervention or standard practices (1) (see [Characteristics of excluded studies](#) and [Figure 1](#)).

### Ongoing studies

We found no ongoing studies.

### Studies awaiting classification

We found one completed, early-phase, randomised, cross-over clinical trial of traditional bed baths versus disposable wet wipes (NCT02984527). This trial compared effects of soap and water versus disposable wipes for "intimate" hygiene using the primary outcome measure of "microbiological counts". Researchers intended to recruit 68 people admitted to hospital for over 48 hours, to administer both interventions with a 24- to 48-hour gap to avoid a cross-over effect. No results have been posted.

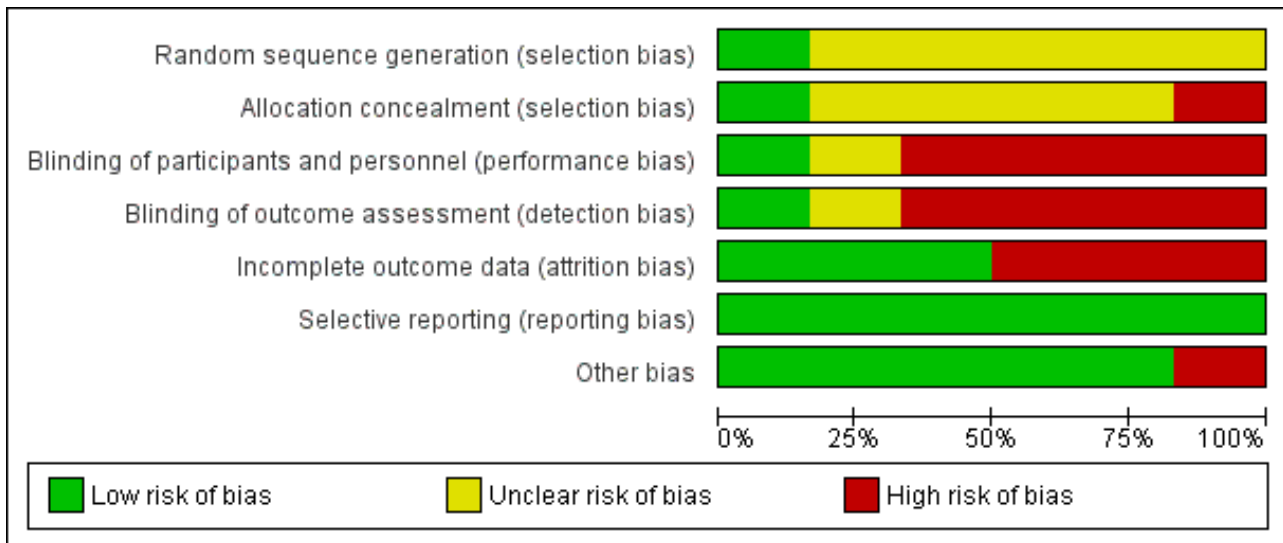
### Risk of bias in included studies

Overall, the risk of bias across all studies was either unclear or low, with the following exceptions: [Hahnel 2017](#), [Gillis 2016](#), and [Carville 2014](#) were judged to be at high risk of attrition bias; [Carville 2014](#), [Hopp 1974](#), [Gillis 2016](#), and [Shishido 2017](#) of performance bias; and [Gillis 2016](#), [Hahnel 2017](#), and [Shishido 2017](#) of detection bias (see [Characteristics of included studies](#)). Please see [Figure 2](#) for our judgements about each 'Risk of bias' item for each included study, and [Figure 3](#) for our judgements about each 'Risk of bias' item presented as percentages across all included studies (risk of bias in included studies).

**Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Boccanfuso 1978	?	?	+	+	+	+	+
Carville 2014	?	-	-	-	-	+	+
Gillis 2016	?	?	-	-	-	+	+
Hahnel 2017	+	+	?	-	-	+	+
Hopp 1974	?	?	-	?	+	+	+
Shishido 2017	?	?	-	-	+	+	-

**Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**



**Allocation**

Five included studies gave no details on how randomisation was carried out (Boccanfuso 1978; Carville 2014; Gillis 2016; Hopp 1974; Shishido 2017), so we have given these studies an unclear assessment for selection bias from random sequence generation. Hahnel 2017 used a computer-generated randomisation schedule with permuted blocks of random sizes and did not disclose these blocks to ensure concealment; hence, we rated this study as having low risk of bias.

One study indicated allocation concealment (Hahnel 2017); another was judged to be at high risk, as the trial register entry (ACTRN12611001089921) reports, "Strictly speaking allocation concealment is not used" (Carville 2014); and four studies offered insufficient details to permit a judgement for risk of selection bias from allocation concealment (Boccanfuso 1978; Gillis 2016; Hopp 1974; Shishido 2017).

**Blinding**

One study was considered at low risk of performance bias because the identity of the coded soap was unknown to all personnel until the study was concluded (Boccanfuso 1978). Another study was at unclear risk: Hahnel 2017 included three groups, one of which continued to use personal hygiene and care products as usual, making this a very different procedure from the other two groups. Four studies were at high risk: Carville 2014, which made no mention of blinding in the paper and in the trial register entry; and Shishido 2017, Gillis 2016, and Hopp 1974, which were considered at high risk due to the nature of the intervention, preventing blinding of the researchers.

Risk of detection bias was considered low in the case of Boccanfuso 1978, when the outcome assessor was not part of the team applying treatment. Risk of detection bias in Hopp 1974 was unclear due to insufficient information. We judged Shishido 2017, Hahnel 2017, Gillis 2016, and Carville 2014 to be at high risk of detection bias, as residents, carers, and study personnel were not blinded to study processes.

**Incomplete outcome data**

Risk of attrition bias is high in Hahnel 2017 (as data from only 117/133 residents were analysed due to factors including hospitalisation, violation of inclusion criteria, and four residents dying), Gillis 2016 (as data from only 150/163 residents were analysed due to factors including change in care home, hospitalisation, and death), and Carville 2014 (as 180 participants were excluded after cluster randomisation and no reference suggests that researchers employed intention-to-treat (ITT) analysis). Risk of attrition bias is low in Shishido 2017, Boccanfuso 1978, and Hopp 1974, given that all randomised participants were accounted for in the analysis.

**Selective reporting**

We did not find any evidence of reporting bias.

**Other potential sources of bias**

We judged Shishido 2017 to be at high risk of other bias due to G power calculation suggesting a minimum sample size of 22, but there were only 21 participants.

**Effects of interventions**

See: [Summary of findings for the main comparison Summary of findings for primary and secondary outcomes](#)

We have created [Summary of findings table 1](#) for the comparison control (standard care or no treatment) versus emollient interventions for our seven primary and secondary outcomes. Three studies - Hahnel 2017, Carville 2014, and Hopp 1974 - provided information about skin dryness. As specified in the protocol, our methods would not have allowed us to combine information from these studies, as they all had different RCT study designs. In any case, insufficient information was available from Carville 2014 and Hopp 1974 to quantify effect sizes. We requested clarification from Carville 2014 on the method of calculation of the study's primary outcome measure - incidence of skin tears. Carville 2014 refers to an "average monthly incidence rate" as



its primary outcome measure, but the units given are the rate per 1000 occupied bed-days rather than per month. Trial authors also excluded those with no skin tears from the control versus intervention comparison, which we regard as a statistical flaw. We requested further information but did not get a response. As indicated in the study notes, [Hopp 1974](#) does not provide information on the precision of outcome measures and was published too long ago for us to obtain this information. We could present only numerical data in a forest plot for [Hahnel 2017](#) (transepidermal water loss, constrictum corneum hydration, Overall Dry Skin Score, and skin surface pH). For the other five studies, we could present only a narrative discussion according to outcome measures.

None of our included studies considered our secondary outcomes - 'erythema' and 'clinical score of itch'. No studies used the other potential tertiary outcomes of 'corneofurfometry', 'types and concentration of stratum corneum lipids', and 'resident microbes'.

## Primary outcome measures

### Frequency of skin damage

Of our primary outcome measures, only one study - [Carville 2014](#) - (N = 1164) considered frequency of skin damage and reported a one-month incidence rate of 5.76 per 1000 occupied beds in the intervention group (moisturisers) compared to 10.57 in the control group (P = 0.004) (ad hoc use of moisturiser or no standardised skin-moisturising regimen) (very low-quality evidence).

### Side effects of the intervention

Only one study - [Hahnel 2017](#) - (N = 133) reported on side effects from interventions. Only four incidents were reported, so we decided to describe them only narratively. There were three events (whole body irritation (severe), itch and redness (mild), and erythema (moderate)) in the structured skin care regimen group consisting of a moisturising body wash containing Shea butter and glycerin used daily and a moisturising leave-on hydrophilic water-in-oil emulsion lotion applied twice daily for two months; and there was one event (mild skin dryness) in the structured skin care regimen group consisting of a glycerin-containing body wash used daily and a water-in-oil emulsion containing emollients and 4% urea applied twice daily for two months (very low-quality evidence).

## Secondary outcome measures

### Transepidermal water loss

This outcome was measured by two studies ([Hahnel 2017](#); [Shishido 2017](#)). [Hahnel 2017](#) measured this outcome in the mid-volar forearm and the lower leg at day 56. This study provided two emollient interventions: (1) a skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea versus usual care, and (2) a skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea. Both of these were compared separately against usual care. No clear difference was found when either intervention was compared to usual care: intervention 1 versus usual care (mid-volar forearm mean difference (MD) -2.70, 95% confidence interval (CI) -7.67 to 2.27; 68 participants; and lower leg MD 0.10, 95% CI -3.55 to 3.76; 67 participants; [Analysis 1.1](#)); and intervention 2 versus usual care (mid-volar forearm MD 0.70, 95% CI -5.81 to 7.21; 70 participants;

and lower leg MD 0.00, 95% CI -3.62 to 3.62; 69 participants; [Analysis 2.1](#)). Values given are temperature-adjusted g/m<sup>2</sup>/h.

[Shishido 2017](#) compared a hot towel applied for 10 seconds after a usual care bed bath versus no hot towel application (usual care bed bath only). Transepidermal water loss was measured before a hot towel was applied to the skin (T1), and 15 minutes after the skin was wiped with a dry towel for one second (T5) in the treatment group, and at the same time points in the comparator group. At time point T5, the mean (SD) in the bed bath plus hot towel group (n = 21) was 8.6 (3.2) compared with 8.9 (4.1) in the bed bath only group (n = 21). The mean difference between groups was -0.30 (95% CI -2.52 to 1.92; [Analysis 3.1](#)). Values given are temperature-adjusted g/m<sup>2</sup>/h.

### Stratum corneum hydration

[Shishido 2017](#), [Gillis 2016](#), and [Hahnel 2017](#) measured stratum corneum hydration. [Hahnel 2017](#) measured at the mid-volar arm and lower leg at day 56. No clear difference was found when either intervention was compared to usual care: intervention 1 versus usual care (mid-volar forearm MD 0.90, 95% CI -2.76 to 4.56; 74 participants; and lower leg MD 3.50, 95% CI -0.65 to 7.65; 73 participants; [Analysis 1.2](#)); and intervention 2 versus usual care (mid-volar forearm MD 1.00, 95% CI -3.03 to 5.03; 75 participants; and lower leg MD -1.10, 95% CI -5.13 to 2.93; 74 participants; [Analysis 2.2](#)). The values given are arbitrary units ranging from 0 to 120 (higher readings indicate higher stratum corneum hydration). The paper states that values of 40 arbitrary units or greater are often considered 'normal', whereas values less than 40 arbitrary units are regarded as typical for dry skin.

In [Gillis 2016](#), study authors reported no statistically significant difference between control (n = 42) and intervention groups (n = 108) using a linear mixed model with treatment group, skin site, and interaction between skin site and treatment as fixed effects, and individual (as there were three sites per person) and ward as random effects (P = 0.412). This outcome was measured before and after implementation of 12 weeks of disposable wash gloves. Arbitrary units in the intervention group compared to the control group were 5.22, 1.84, and 16.33 units higher for the leg, hand, and cheek, respectively. However, data were presented only on a graph, and it is unclear if the data provided were means and standard errors, or other measures. Hence, these data could not be analysed.

In [Shishido 2017](#), stratum corneum hydration was measured immediately after the skin was wiped three times (T3), immediately after the skin was wiped with a dry towel (T4), and 15 minutes after T4 (T5). At T3, the mean stratum corneum hydration in the bed bath plus hot towel application was 104.4 (SD 8.1) versus 94.9 (15.7) in the bed bath only group, showing significantly more stratum corneum hydration in the hot towel group: MD 9.50, 95% CI 1.94 to 17.06 ([Analysis 3.2](#)). At T4, the mean stratum corneum hydration in the bed bath plus hot towel application was 67.3 (SD 11.1) versus 59.7 (12.4) in the bed bath only group, showing significantly more stratum corneum hydration in the hot towel group: MD 7.60, 95% CI 0.48 to 14.72 ([Analysis 3.2](#)). However, at T5, the mean difference between groups was no longer statistically significant: MD -0.40, 95% CI -4.76 to 3.96; mean 40.2 (SD 8.0) in the hot towel group versus 40.6 (6.3) in the bed bath only group ([Analysis 3.2](#)). Reference values were greater than 50 arbitrary units for enough moisture, 35 to 50 arbitrary units for dry, and less than 35 arbitrary units for very dry.

### Clinical score of dryness

Three of the six studies observed skin condition with reference to xerosis using different methods. [Hahnel 2017](#) used a 5-point scale: 0 indicates no skin dryness, and 4 indicates advanced skin roughness, large scales, inflammation, and cracks. When comparing intervention 1 with usual care (at day 56 ± 4), [Hahnel 2017](#) found less dryness in the right forearm (MD -0.60, 95% CI -1.02 to -0.18; 76 participants), left lower leg (MD -0.60, 95% CI -1.08 to -0.12; 73 participants), and trunk (MD -0.40, 95% CI -0.70 to -0.10; 75 participants), but the difference was not significant in the left forearm (MD -0.30, 95% CI -0.94 to 0.34; 76 participants) nor in the right lower leg (MD -0.20, 95% CI -0.87 to 0.47; 74 participants) ([Analysis 1.3](#)). When intervention 2 was compared with usual care, less dryness was found in the left lower leg (MD -0.50, 95% CI -0.96 to -0.04; 75 participants), the right forearm (MD -0.60, 95% CI -1.05 to -0.15; 77 participants), the left forearm (MD -0.60, 95% CI -1.05 to -0.15; 77 participants), and the trunk (MD -0.30, 95% CI -0.60 to -0.00; 74 participants), but no clear difference was observed in the right lower leg (MD -0.40, 95% CI -0.86 to 0.06; 76 participants) ([Analysis 2.3](#)). This evidence was assessed as low quality.

[Boccanfuso 1978](#) found, after 10 applications, that the 52 legs on which the moisturising soap bar was used had significantly less skin flaking relative to baseline (mean of 3 reduced to 1.9) than the 52 legs on which the placebo soap bar was used (mean of 2.92 reduced to 2.21) ( $P = 0.05$ ) (6-point numerical scale: 0 = no flaking, 5 = crusting). [Hopp 1974](#) found improvements in all five intervention groups with regard to dryness of skin score in 60 participants (lotion  $P < 0.0001$ , water soak  $P = 0.0121$ , water soak and lotion  $P < 0.0001$ , oil soak  $P = 0.0003$ , and oil soak and lotion  $P < 0.0001$ ) at eight days. When dryness was compared pair-wise between intervention groups, there were three significant findings. The water soak was more effective than the water soak and lotion ( $P = 0.0002$ ), the water soak was more effective than the water soak and lotion ( $P = 0.0144$ ), and the oil soak was more effective than the water soak and lotion ( $P = 0.0090$ ). No further numerical data were provided.

### Tertiary outcome measures

#### Skin surface pH

Only [Hahnel 2017](#) measured skin surface pH (using the Skin-pH-Meter1 PH 905, Courage + Khazaka, Cologne, Germany). There was no significant difference between intervention 1 and usual care when the mid-volar forearm (MD 0.00, 95% CI -0.30 to 0.30; 74 participants) or the lower leg (MD -0.10, 95% CI -0.38 to 0.18; 71 participants) ([Analysis 1.4](#)) was assessed. A similar finding was reported when intervention 2 was compared with usual care: mid-volar forearm (MD 0.20, 95% CI -0.10 to 0.50; 75 participants) and lower leg (MD 0.20, 95% CI -0.08 to 0.48; 72 participants) ([Analysis 2.4](#)).

## DISCUSSION

### Summary of main results

We found very few studies that met our inclusion criteria (only six studies, which included 1598 participants). None of the included studies measured our secondary outcomes erythema and clinical score of itch. Only one tertiary outcome was reported. If trials did assess an outcome of interest, the number of trials measuring the outcome was never more than three, and unfortunately, we were unable to meta-analyse any of the study results due to

heterogeneity in treatments given and outcomes assessed. Only one study reported side effects from interventions.

Evidence in this review is limited by its low/very low quality, and it is derived only from older people living in care (both nursing homes and aged care settings); none of the studies used a hospital setting. Only one study assessed an intervention that avoids the need for drying. No studies investigated the use of other methods of cleansing (e.g. bed bath wipes, no-rinse cleansers) nor alternative emollient preparations (e.g. gel, aerosol).

In five studies, duration of treatment ranged from five days to six months; only one of these had follow-up post treatment (one to eight days from the end of treatment). Outcomes in the hot towel study were measured 15 minutes after the skin was wiped with a dry towel. More detailed results are found in [Summary of findings for the main comparison](#).

Only two studies assessed our primary outcomes (frequency of skin damage and side effects). We graded evidence from these studies as very low quality, meaning we are uncertain of the following results: one study (984 participants) ([Carville 2014](#)) found that usual care plus the application of a commercially available, pH-neutral, perfume-free moisturiser reduced skin tears when compared with usual care (i.e. ad-hoc use of a moisturiser or no standardised skin-moisturising regimen). Side effects were measured in only one study (133 participants): itch (mild), redness (mild/moderate), irritation (severe), and mild skin dryness were reported in two intervention groups that commenced two structured skin care regimens comprising a moisturising body wash used alongside a body lotion (all four products had different ingredients). This was compared with no side effects reported in the usual care (usual personal hygiene and care products) group.

This study also assessed transepidermal water loss (TEWL) in the mid-volar forearm (106 participants) and lower leg (105 participants), and found there may be no differences between treatment groups and usual care groups. Another study (42 participants) found that mean TEWL may be similar when participants have a hot towel applied for 10 seconds after a usual care bed bath compared to when they have a usual care bed bath only. Both studies are based on low-quality evidence.

Two studies indicated that when compared with usual care (lotion alone or water soak or oil soak (with or without the addition of lotion)) or no intervention (respectively) (60 participants), moisturising skin hygiene products, with or without regularly applied emollients (133 participants), may have a therapeutic effect on improving xerosis, measured against a clinical score of dryness. A third study indicates that adding an emulsifier and a humectant to a moisturising soap bar may improve xerosis compared with using a soap bar without these additives (52 participants). We graded evidence as low quality for this outcome.

Three studies (266 participants) found no clear difference in stratum corneum hydration (SCH) when the following treatments were compared with usual care: different skin care regimens; use of wash gloves; and single application of hot towel to the skin. However, evidence quality was very low, so we are uncertain of this result.

## Overall completeness and applicability of evidence

We identified only six eligible studies; their results provide only a small insight into the effects of a limited number of potential hygiene and emollient interventions. There was heterogeneity in intervention ingredients, comparison groups, and body areas treated. Therefore meta-analysis was not possible, and a narrative review is presented.

In terms of addressing the objectives of this review, there were a number of shortcomings. The following outcomes were not assessed by any of the included studies: erythema and clinical score of itch. Two outcome measures (frequency of skin damage and side effects) were reported by single studies. Furthermore, there was limited use of established and validated outcome measures in the outcomes reported by our included studies, which limits the legitimacy of the results.

Duration/follow-up of intervention was short for most studies: five days (Boccanfuso 1978), 12 days (Hopp 1974), eight weeks (Hahnel 2017), 12 weeks (Gillis 2016), and six months (Carville 2014). Only one of these had follow-up post treatment (of one to eight days from end of treatment). In Shishido 2017, the intervention was given once (hot towel applied for 10 seconds) and outcomes were measured 15 minutes after the skin was wiped with a dry towel.

Only one study assessed the use of bed bath gloves, which prevent the need for drying after washing. No studies investigated the use of other methods of cleansing (e.g. bed bath wipes, no-rinse cleansers) nor alternative emollient preparations (e.g. gel, aerosol). All studies were conducted in residential care, so we cannot be sure that the results apply to a population based in a hospital setting. Participants were from five countries, but the ethnicity of participants in the included trials was not reported. Two studies were conducted in relatively hot climates (Western Australia and Arizona, USA), so results may be limited to a small subset of skin types/ethnicities and may not be applicable in countries with different climates. In studies where gender was reported, most participants were female; this may have had implications, given that hormones impact skin health, and postmenopausal women experience significant reduction in skin elasticity, moisture, and thickness and impaired wound healing (Farage 2015).

It remains unclear how hygiene interventions differ from one other in terms of the emollient or wash product used and how they are delivered.

## Quality of the evidence

The main methodological weaknesses of our included studies were as follows.

- Unclear methods of randomisation due to lack of information provided in papers and inability to contact study authors.
- Lack of information on the precision of group difference estimates.

The quality of evidence was judged very low for our primary outcomes due to the small number of eligible studies and the absence of reportable outcome measures. Of the six studies, only two reported on our primary outcome measures; Carville 2014 reported on the frequency of skin damage (skin tears), and Hahnel 2017 reported on side effects of the intervention. Skin tears were inconsistently reported per 1000 occupied bed-days instead of

over a six-month period, and participants with no skin tears were excluded (meaning only 424 of the 984 participants enrolled in the study were included in the analysis). Reasons for this were not explained, and so, due to the imprecision of the outcome measure and the risk of bias, the data were not analysed further. With regard to side effects, one study of 133 participants reported on this outcome across the two intervention groups and identified four incidents: (1) whole body irritation (severe), (2) itch and redness (mild), (3) erythema (moderate) in group I, and (4) skin dryness (mild) in group II. In both cases, the quality of evidence was graded as very low due to only one study and few participants contributing to this measure (Hahnel 2017).

Secondary outcome measures of TEWL were reported by Shishido 2017 and Hahnel 2017; SCH by Gillis 2016, Shishido 2017, and Hahnel 2017; and clinical score of dryness by Boccanfuso 1978, Hahnel 2017, and Hopp 1974. The quality of evidence for TEWL and SCH was considered low due to small sample sizes, diversity of the intervention delivered, and frequency of intervention and differences in data collection points.

With regard to a clinical score of dryness, Hopp 1974 offered insufficient information pertaining to the study data, such as standard deviations or standard errors, to permit further analysis. From one of their published tables, it might have been possible to extract this information from the presented t-statistics and P values. However, no degrees of freedom were presented and the t-statistics and P values presented were not consistent with the degrees of freedom that would be obtained from the stated sample size. The paper was published too long ago for us to obtain missing information from the study authors. Risk of bias regarding selection and detection was unclear in Boccanfuso 1978, and attrition was a problem in Hahnel 2017, with data from only 117 out of 133 residents analysed due to hospitalisation, violation of inclusion criteria, and participant deaths. All three studies contributed fewer than 245 participants (given attrition), and quality of evidence for skin dryness was considered low.

Outcome measures were graded low or very low due to a range of factors including imprecision as outcomes were measured by one to three studies, risk of attrition bias, and performance and detection bias.

Loss to follow-up was an issue in Hahnel 2017 as data from 117 of 133 residents was analysed due to factors including hospitalisation, violation of inclusion criteria, and four residents dying. Similarly, 57% of participants in Carville 2014 were excluded from the analysis of the primary study outcome, which means the group comparison presented is potentially biased.

Hahnel 2017 used validated outcome measures in accordance with published guidelines including the Overall Dry Skin Score (Serup 1995), as judged by a trained assessor and validated instrumental measures of stratum corneum hydration, skin surface pH, and transepidermal water loss alongside skin surface temperature. Carville 2014 used the validated STAR Skin Tear Classification System (Carville 2007). Outcome measures in two studies were not validated according to available literature (Boccanfuso 1978; Hopp 1974). Specifically, there is no evidence of validation of the General Foot Condition Questionnaire and Dryness Scale (0 to 7) used by Hopp 1974. The Modified Skin Flaking Scale (0 to 5) used by Boccanfuso 1978 is reported to be derived from the work of Rieger 1974, although the cited paper contains no relevant



information. Subjective participant evaluation was sought only by [Hopp 1974](#) through questions about foot comfort, including painful toenails, burning, itching, coldness, or pain. Although [Gillis 2016](#); and [Shishido 2017](#) used validated measures of TEWL and SCH, there is no evidence that study authors followed best practice guidance ([du Plessis 2013](#)).

[Hahnel 2017](#) conducted an exploratory study with no formal sample size calculation. [Carville 2014](#) states that sample size was deemed sufficient to detect a difference in incidence rates between groups at the 5% level with 80% power and a significance level of  $P = 0.05$ . [Shishido 2017](#) did a power calculation that suggested a minimal sample size of 22, but the study included only 21 participants.

Justification of sample size is not provided by [Hopp 1974](#), [Gillis 2016](#), or [Boccanfuso 1978](#).

In summary, the absence of information on the precision of intervention effect estimates in the included studies means that available evidence was of limited value. Data synthesis was not possible, and individual studies were not sufficiently robust to allow definitive conclusions about the effectiveness of interventions.

### Potential biases in the review process

Our broad searches yielded limited data. In screening studies for inclusion, we were careful to include all studies, irrespective of types of interventions and outcomes, as long as they were randomised controlled trials of 'skin care' interventions conducted in a care setting among people 60 years of age and older. Thus any pre-conceived idea on types of hygiene intervention or use of outcome measures has not influenced the results of this review. Bias may have been introduced, as we did not review the grey literature (for the reasons cited above).

### Agreements and disagreements with other studies or reviews

This review focused on the effects of hygiene and emollient interventions for maintaining skin integrity among older people in hospital and residential care settings. Our systematic search for allied studies or reviews generated few studies in this area. A review of systematic reviews ( $n = 1$ ) and randomised or non-randomised controlled trials ( $n = 10$ ) concerning care home residents aged 65+ years assessed the effectiveness of topical skin care regimens ([Hodgkinson 2007](#)). Most studies focused on the role of skin cleansers in preventing dermatitis, skin tears, and incontinence-associated skin damage. Interventions included absorbent products, no-rinse cleansers, emollients and emollient soaps, and structured skin care regimens. Outcome measures included assessment of general skin condition, pressure ulcers, skin tears, dermatitis, and dry skin. In an integrative review of skin hygiene practices for older people ([Coddell 2015](#)); seven included studies investigated the use of different bathing products. As with [Hodgkinson 2007](#), [Coddell 2015](#) concludes that the quality of available evidence is low, and that much further research is needed.

[Kottner 2013](#) systematically reviewed 33 primary intervention studies using skin care products with people older than 50 years of age in any setting, reporting on dry skin, incontinence-associated dermatitis, and superficial ulceration. Review authors concluded that the methodological limitations of these studies made the evidence weak but tentatively suggested that cleansing the skin

with syndets or amphoteric surfactants as an alternative to soap and water improved xerosis and offered some skin protection. Humectant emollients consistently showed statistically significant improvements in xerosis. Occlusive skin barrier products reduced skin injury when compared with standard or no treatment. This is congruent with our conclusion that in residential care settings for older people, washing/soaking using moisturising cleansers/oil with or without emollient therapy may have a positive effect on skin condition, specifically to alleviate dry skin (xerosis), compared with no intervention or standard care. As with our review, [Kottner 2013](#) concluded that there is a need for further research including more studies to elicit the value of skin-cleansing regimens and emollients when compared with each other. In a systematic review of 41 studies of interventions for prevention of dry skin, incontinence-associated dermatitis, and skin injury in adults, rather than specifically older people, in acute or long-term care settings, [Lichterfeld 2015](#) reported that the methodological quality of included studies was variable. Nevertheless, in contrast to our findings, these review authors were able to propose a two-step approach to general and special skin care for skin that is too dry or too moist. An evaluation of the effect of an emollient containing urea, ceramide 3, and lactate on skin barrier structure and function in older people with dry skin by Danby in 2014 has yet to be published. A small but growing body of evidence suggests that in younger age groups, emollient treatments can prevent the re-emergence of atopic dermatitis ([Akerstrom 2015](#); [Wiren 2009](#)). It is possible that this knowledge may be valuable when applied to the care of older people's skin, but this would require further investigation. As noted earlier, there is considerable research on care of the skin of older people with incontinence and those at high risk of developing pressure ulcers, but this important literature is beyond the scope of this review. A recent Cochrane Review on emollients and moisturisers for eczema reported a highly diverse range of effects on skin condition from minimal to substantial ([van Zuuren 2017](#)).

## AUTHORS' CONCLUSIONS

### Implications for practice

This review collates evidence from six trials. Given the ageing population ([United Nations 2017](#)), increasing recognition of the importance of maintaining skin health in older people, and the fact that maintaining skin hygiene and comfort is one of the cornerstones of care provided in residential and hospital settings ([Coddell 2015](#)), it is surprising that there is not more evidence to underpin best practice.

We do not have sufficient evidence to determine the effects of hygiene and emollients in maintaining skin integrity among older people in residential and hospital settings. Reporting of harm from these interventions was poor. Only one study reported side effects: four instances (mild itch, mild to moderate redness, mild skin dryness, and severe irritation) were reported across two intervention groups.

We are not certain of the effects of the assessed interventions on frequency of skin damage, side effects, and stratum corneum hydration (SCH) due to the very low quality of the evidence provided for these outcomes.

In residential care settings for older people, we found low-quality evidence for the following interventions and outcomes.

- When compared with usual care (continuing with usual personal hygiene and care products), washing using moisturising cleansers containing ingredients that have emollient or humectant properties, or both, alongside the use of moisturising body lotion, may improve skin dryness on certain parts of the body but may make no apparent difference in transepidermal water loss (TEWL).
- Mean TEWL may be similar when a hot towel is applied to the body area for 10 seconds after a usual care bed bath and when a usual care bed bath alone is provided.
- A moisturising soap bar with an added emulsifier and humectant may improve skin dryness compared with a soap bar without these added ingredients.
- Lotion alone or water soak or oil soak (with or without the addition of lotion) may improve skin dryness when compared with usual care no treatment.

The following outcomes were not assessed by any of the included studies: erythema and clinical score of itch.

Firm conclusions cannot be drawn from the included studies due to methodological weaknesses and absence of information on effect sizes and precision in the study reports.

### Implications for research

A small number of studies met our inclusion criteria, and these all had some methodological weakness. There is therefore a significant opportunity to improve research design to evaluate the effectiveness of hygiene and emollient interventions for maintaining or improving skin integrity among older people in residential care and hospital settings.

Future randomised controlled studies should focus on pragmatically deliverable interventions such as use of disposable bed bath/wet wipes, which obviate the need to towel-dry skin, and use of differing emollient formulations such as gels and aerosols. The study awaiting classification - [NCT02984527](#) - is assessing the effects of intimate hygiene with soap and water versus intimate hygiene with pre-packaged disposable bed bath/wet wipes in a randomised cross-over trial.

There is a need to agree upon and use a set of core outcome measures, so that in the future, meta-analysis of studies will be possible. Vital outcomes including clinical measures of skin integrity (skin dryness, erythema, and skin tears, for example) and objective measures of skin barrier function, namely, stratum corneum hydration and transepidermal water loss, are now available, accompanied by clear guidelines for using these

instruments in real-world settings ([du Plessis 2013](#)). Self-reported scores of itch should be measured and side effects must be assessed in all future studies.

Research is needed on the effects of hygiene and emollient interventions among persons of different ethnicities and skin types, including participants in a variety of settings (e.g. countries with different climates and hospital settings, as well as residential settings).

Future studies should be designed more robustly. In particular, researchers must use and accurately report adequate methods of random allocation, allocation concealment, and methods to ensure blinding. It is important that these studies include appropriate controls (i.e. standard care) and report sufficient information related to the precision of group difference estimates (e.g. standard deviation). Because attrition bias was high, future studies should try to minimise the number of dropouts and report reasons for dropouts. Many of the included studies had a small sample size, resulting in imprecise results. Further studies should ensure that researchers perform sample size calculations to adequately detect important differences between groups.

Such studies should develop a standardised language of skin care and skin care products that can be used when clinical research is planned and undertaken. In addition, we suggest the need for common definitions of terms such as 'skin damage' and 'skin breakdown', which are frequently seen in publications. This will support the development of evidence-based guidelines for providing skin care to our ageing population ([Kottner 2016](#)).

In conclusion, there is much scope to undertake intervention studies to evaluate skin hygiene and emollient regimens with the potential to maintain and promote skin health among older people living in residential and hospital settings.

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\* Indicates the major publication for the study

**CHARACTERISTICS OF STUDIES**
**Characteristics of included studies [ordered by study ID]**
**Boccanfuso 1978**

Methods	Design: within-participant trial (all patients had each treatment randomly assigned to each leg)
	Unit of randomisation: patient legs



**Boccanfuso 1978** (Continued)

Unit of analysis: patient legs

Participants	<p><b>Setting</b></p> <p>A home for the elderly in Phoenix, AZ</p> <p><b>Inclusion criteria of the trial</b></p> <ul style="list-style-type: none"> <li>• Condition/clinical state specified: severe skin xerosis on the anterior tibia</li> <li>• Diagnostic criteria: based on clinical judgement of a trained scorer (0 = no flaking, 1 = barely perceptible flaking, 2 = very slight flaking, 3 = mild flaking, 4 = moderate flaking, 5 = severe flaking) (based on Rieger et al 1974); scale was adjusted as follows to fit the higher level of xerosis in the population (0 = no flaking, 1 = mild flaking, 2 = moderate flaking, 3 = severe flaking, 4 = very severe flaking, 5 = crusting)</li> </ul> <p><b>Participants</b></p> <p>52 participants (104 legs)</p> <p>0 withdrawals</p>	
Interventions	<p><b>Intervention</b></p> <p>A moisturising soap bar, containing the following moisturising ingredients - “a special protein”, a lanolin derivative, and glycerin - was applied to one leg of each participant twice daily under supervision. Ten applications were performed</p> <p>Treatment group N = 52 legs</p> <p><b>Control intervention</b></p> <p>The same as the treatment group intervention, minus the moisturising ingredients listed above</p> <p>Control group N = 52 legs</p> <p>5 days of treatment</p>	
Outcomes	<p>Our secondary outcome of interest - skin dryness - was measured by using the xerosis severity score (adapted from <a href="#">Rieger 1974</a>). This outcome was measured at baseline and after 6 and 10 applications of the intervention; exact timing in terms of the number of hours or days is not provided in the study report</p>	
Notes	<p>Skin dryness: group means were presented without standard deviations, and the paper was published too long ago for us to obtain missing information from study authors</p> <p>Study dates are not provided</p> <p>Support from an industry statistician is reported</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	<p>Quote: "in each subject, the moisturising soap bar was randomly assigned to one of the legs and a placebo bar [was] assigned to use on the other leg"</p> <p>Comment: no further details provided; therefore insufficient information about sequence generation to permit a judgement of 'low risk' or 'high risk'</p>
Allocation concealment (selection bias)	Unclear risk	This was not reported

**Boccanfuso 1978** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "identity of the coded soap bars was unknown to all personnel involved in the study until it was concluded" (p704)  Comment: likely blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Although there is no record of the outcome assessor being blinded to allocation, this person was not part of the team applying the treatment. Furthermore, the soap bars were coded and ingredients were unknown to the team throughout the study. Therefore we judge it unlikely that the assessor could have been aware of allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the study
Selective reporting (reporting bias)	Low risk	There is one study outcome, and this was reported
Other bias	Low risk	The study appears to be free of other sources of bias

**Carville 2014**

Methods	Design: cluster RCT  Unit of randomisation: aged care facilities  Unit of analysis: patient
Participants	<p><b>Setting</b></p> <p>Aged care residential facilities in Western Australia</p> <p><b>Inclusion criteria of the trial</b></p> <ul style="list-style-type: none"> <li>Residents in 14 specified residential care facilities</li> <li>Not receiving other conflicting skin treatments</li> </ul> <p>Diagnostic criteria: no pre-existing skin condition</p> <p><b>Participants</b></p> <p>543 randomised to intervention group</p> <p>123 withdrawals/excluded (86 no consent obtained, 5 pre-existing skin conditions, 6 transferred residents, 26 respite residents)</p> <p>621 randomised to control group</p> <p>57 withdrawals (4 transferred residents, 53 respite residents)</p>
Interventions	<p><b>Intervention</b></p> <p>'Usual' care + twice-daily application of a commercially available, standardised pH (5 to 6) neutral, perfume-free moisturising lotion (Abena) on the extremities using a gentle downward motion by staff or residents</p> <p>N = 543</p> <p><b>Control intervention</b></p>

**Carville 2014** (Continued)

Ad hoc or no standardised skin-moisturising regimen (usual care)

N = 621

Treatment duration was 6 months

Outcomes	Our primary outcome of interest was measured: skin damage (tears). Average monthly incidence of skin tears (as recorded by clinical staff according to the STAR Skin Tear Classification) over the 6-month study period reported as (number of skin tears/residents occupied bed days) × 1000 occupied bed-days
Notes	<p>Skin damage: study authors did not respond to request for clarification on how their outcome measure was calculated. Additionally, their analysis is potentially biased, as they excluded participants with no skin tears from their comparison</p> <p>The study was conducted from October 2011 to March 2012</p> <p>Funding was provided by The Wound Innovation CRC, as acknowledged by the authors of the study</p> <p>Trial protocol retrospectively registered: ACTRN12611001089921</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote: "one facility from each of these matched pairs was randomised into the intervention group and the other into the control group"</p> <p>Comment: it is unclear how random sequence generation was performed; we therefore have insufficient information to judge 'low risk' or 'high risk'</p>
Allocation concealment (selection bias)	High risk	Trial register entry (ACTRN12611001089921) reports, "Strictly speaking allocation concealment is not used"
Blinding of participants and personnel (performance bias) All outcomes	High risk	No mention of blinding in the paper; the trial register entry (ACTRN12611001089921) states, "Open (masking not used)"
Blinding of outcome assessment (detection bias) All outcomes	High risk	No mention of blinding in the paper; the trial register entry (ACTRN12611001089921) states, "Open (masking not used)"
Incomplete outcome data (attrition bias) All outcomes	High risk	No evidence ITT was used. 180 people were excluded post randomisation
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	We did not read anything that suggested other possible biases

**Gillis 2016**

Methods	Design: cluster RCT  Unit of randomisation: ward  Unit of analysis: resident
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**Gillis 2016** (Continued)

Participants	<p><b>Setting</b></p> <p>Six wards within 2 nursing homes in Flanders (Northern Belgium)</p> <p><b>Inclusion criteria of the trial</b></p> <ul style="list-style-type: none"> <li>Residents in 6 wards in 2 specified residential nursing homes</li> </ul> <p><b>Participants</b></p> <p>122 randomised to intervention group</p> <p>14 withdrawals (5 no informed consent, 3 died, 2 stopped the intervention, 2 hospitalised)</p> <p>46 randomised to control group</p> <p>4 withdrawals (1 moved to another nursing home, 1 resident hospitalised, 2 residents died)</p>	
Interventions	<p><b>Intervention</b></p> <p>Usual care (traditional bed bath) with use of "wash gloves" containing aqua, propylene glycol, co-co-glucoside, phenoxyethanol, parfum, benzoic acid, polyaminopropyl biguanide, octyldodecanol, aloe barbadensis, glycine soja oil, dehydroacetic acid, sodium lauroamphoacetate, <i>Calendula officinalis</i> extract, <i>Tilia cordata</i> extract, <i>Melissa officinalis</i> extract, <i>Hamamelis virginiana</i> extract, <i>Echinacea purpurea</i> extract, <i>Chamomilla recutita</i> extract, <i>Centella asiatica</i> extract, aloe barbadensis gel, tocopherol</p> <p><b>Control intervention</b></p> <p>Usual care</p> <p>Most of the residents had a shower or bath once a week (defined as frequent bathing)</p>	
Outcomes	<p>Secondary outcome measure stratum corneum hydration was measured using a MoistureMeter SC at 3 skin sites (hand, leg, and cheek) pre and post intervention period of 12 weeks</p>	
Notes	<p>The study was conducted from March and May 2014</p> <p>The study was funded in part by Curando vzw to cover the cost of the MoistureMeter SC and writing of the manuscript</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: "a single blind or double blinded design was not possible for this study but we are convinced that the use of independent researchers and the use of the MoistureMeter SC as tool are strengths"</p> <p>Comment: lack of blinding resulted in the 'high risk' judgement for this study</p>
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding

**Gillis 2016** (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	150 out of 163 participants completed the study. There is no reference to the study authors employing ITT analysis
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	We did not read anything that suggested other possible biases

**Hahnel 2017**

Methods	Design: RCT with 3 parallel groups  Unit of randomisation: residents  Unit of analysis: residents
Participants	<p><b>Setting</b></p> 10 institutional long-term-care facilities in Germany
	<p><b>Inclusion criteria of the trial</b></p> <ul style="list-style-type: none"> <li>Resident in a study facility</li> <li>65+ years old</li> <li>Overall Dry Skin Score of 2 to 4</li> </ul>
	<p><b>Participants</b></p> 133 residents  16 withdrawals
Interventions	<p><b>Intervention</b></p> Group 1: (n = 40) structured skin care regimen consisting of a moisturising body wash containing Shea butter and glycerin used daily and a moisturising leave-on hydrophilic water-in-oil emulsion lotion (body lotion) applied twice daily for 8 weeks
	<p><b>Intervention</b></p> Group 2: (n = 41) structured skin care regimen consisting of glycerin-containing body wash used daily and a water-in-oil emulsion lotion (body lotion) containing emollients and 4% urea applied twice daily for 8 weeks
	<p><b>Control intervention</b></p> Group 3: (n = 36) skin care as usual
Outcomes	Overall Dry Skin Score ( <a href="#">Serup 1995</a> ): a score of 0 to 4 allocated to scaling, roughness, redness, and cracks/fissures (allowing a total score of between 0 and 16)  Stratum corneum hydration (measured in arbitrary units from 0 (no water) to 120 (on water)) using the Corneometer CM 825 (Courage + Khazaka, Cologne, Germany) and transepidermal water loss (measured in temperature adjusted g/m <sup>2</sup> /h) using the Tewameter TM 300 (Courage + Khazaka, Cologne, Germany) measured at baseline (day 0) and day 56 ± 4  Side effects of the intervention

**Hahnel 2017** (Continued)

Skin surface pH at day 56 ± 4, measured with the Skin-pH-Meter PH 905 (Courage + Khazaka, Cologne, Germany)

All participating residents were examined at baseline and after 4 and 8 weeks

Instrumental skin barrier measurements were performed at baseline and after 8 weeks

Notes

All products were commercially available

All biophysical measurements were conducted at baseline (day 0) and day 56 ± 4 (end of the study) in duplicates at the right arm and right lower leg skin areas

Functional assessments using the Braden Scale and the Barthel Index were conducted. Six-item cognitive impairment test completed

Galderma Pharma and the Clinical Research Center for Hair and Skin Science, Department of Dermatology and Allergy, Charité - Universitätsmedizin Berlin, funded the study

Trial register number: NCT02216526

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "participants in each of the ten nursing homes were randomly assigned to one of two intervention groups (Groups I and II) or to the control group (Group III) with a 1:1:1 allocation ratio as per computer generated randomization schedule using permuted blocks of random sizes"  Comment: randomisation method was described
Allocation concealment (selection bias)	Low risk	Quote: "the block sizes were not disclosed to ensure concealment"  Quote: "after the investigator confirmed the resident's eligibility for participating in the intervention study at day 0, the study assistant allocated the resident to the lowest randomization number available on the randomization list and opened an opaque envelope to ensure allocation concealment"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Three groups, 1 of which continued to use personal hygiene and care products as usual, so this procedure is very different from the other two groups
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "the randomisation schedule remained blinded for investigators who performed the dermatological examinations and clinical assessments" However,  Quote: "detection bias may have occurred due to residents, caregivers, and study personnel being un-blinded to study procedures"  Quote: "could not exclude the possibility that investigators systemically changed their Overall Dry Skin Scorings during the study"  Comment: these factors are likely to make the study at high risk of detection bias
Incomplete outcome data (attrition bias) All outcomes	High risk	Data from only 117 of 133 residents were analysed due to factors including hospitalisation, violation of inclusion criteria, and 4 residents dying  There is no reference to trial authors employing ITT analysis

**Hahnel 2017** (Continued)

Selective reporting (re-reporting bias)	Low risk	The protocol has been previously published
Other bias	Low risk	We did not read anything that suggested other possible biases

**Hopp 1974**

Methods	<p>This is an RCT</p> <p>Unit of randomisation was the patients' feet</p> <p>Unit of analysis was the patients' feet</p>
Participants	<p><b>Setting</b></p> <p>2 nursing homes in the USA</p> <p><b>Inclusion criteria of the trial</b></p> <ul style="list-style-type: none"> <li>• Resident in study nursing homes</li> <li>• 60 years of age or older</li> <li>• Without critical illness, amputation, or draining foot lesion</li> </ul> <p><b>Participants</b></p> <p>60 participants (120 feet)</p> <p>0 withdrawals</p>
Interventions	<p><b>Control intervention</b></p> <p>Group A control (no intervention)</p> <p><b>Intervention</b></p> <p>Group B lotion</p> <p>Group C water soak</p> <p>Group D water soak + lotion</p> <p>Group E oil soak</p> <p>Group F oil soak + lotion</p> <p>(n = 20 feet in each group)</p> <p>Treatment was given daily for 12 days</p>
Outcomes	<p>Our primary outcome of interest (skin damage (dryness)) was measured</p> <p>General Foot Condition Questionnaire</p> <p>Dryness Scale (1 = oily; 2 = normal, appears hydrated; 3 = dry-rough texture, lack of moisture; 4 = scaly + - scant white scales; 5 = scaly ++ - few yellow, oily scales; 6 = scaly +++ - moderate to many white scales; 7 = scaly ++++ many thick yellow scales). The outcome was measured at baseline, at day 1, and at day 8 after the conclusion of the interventions</p>
Notes	<p>Skin dryness: from one published table, it might have been possible to extract this information from presented t-statistics and P values. However, no degrees of freedom were presented, and the t-statistics and P values presented were not consistent with the degrees of freedom that would be obtained</p>

**Hopp 1974** (Continued)

from the stated sample size. The paper was published too long ago for us to obtain missing information from the study authors

Study dates are not reported

Funding sources are not reported

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "each foot of each subject was randomly assigned" to 1 of 6 groups  Comment: no further detail was provided; therefore information was insufficient to permit a judgement of 'low risk' or 'high risk'
Allocation concealment (selection bias)	Unclear risk	Quote: "each foot of each subject was randomly assigned" to 1 of 6 groups  Comment: no further detail was provided; therefore information was insufficient to permit a judgement of 'low risk' or 'high risk'
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is unlikely that researchers could have been blinded due to the nature of the interventions
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the panel of assessors were also the researchers. Information is insufficient to permit a judgement of 'low risk' or 'high risk'
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the study
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	We did not read anything that suggested other possible biases

**Shishido 2017**

Methods	Design: cross-over trial  Unit of randomisation: individual  Unit of analysis: resident
Participants	<b>Setting</b>  Two long-term healthcare facilities in Japan  <b>Inclusion criteria of the trial</b> <ul style="list-style-type: none"> <li>• Skin on the inner side of the forearm should be intact with normal temperature sensation with no rashes, wounds, allergies, itchy sensation, or rough or cracked surfaces, nor requiring ointment application</li> <li>• Able to independently perform activities of daily living and to understand instructions</li> </ul> <b>Participants</b>



**Shishido 2017** (Continued)

Twenty-one, some randomly receiving the intervention on one day and the control on the next, others receiving the 2 conditions in the reverse sequence

Interventions	<p><b><u>Intervention</u></b></p> <p>A hot towel for 10 seconds after a usual care bed bath</p> <p><b><u>Control intervention</u></b></p> <p>Usual care bed bath</p>
Outcomes	<p>Our secondary outcome measure stratum corneum hydration was measured using a corneometer (CM825 manufactured by Courage and Khazaka, Cologne, Germany)</p> <p>Tewameter TM300 manufactured by Courage &amp; Khazaka was used to measure TEWL</p>
Notes	<p>Conducted between April and June 2015</p> <p>There were five data collection points: before bed bath (T1), immediately after applying a hot towel to the skin (T2), immediately after wiping the skin 3 times (T3), immediately after wiping the skin with a dry towel (T4), and at 15 minutes after T4 (T5)</p> <p>Study dates are not reported</p> <p>Funding sources are not reported</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote: "they were randomly allocated to a group in which the first type of bed bath preceded the second type and in the other group in which the sequence was reversed"</p> <p>Comment: method not described</p>
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: "the same researcher performed all measurements to avoid errors due to procedural deviation"</p> <p>Comment: it was not possible to blind participants to applying or not applying a hot towel for 10 seconds. It would not be possible to blind the researcher, as measurements included one immediately after application of the towel</p>
Blinding of outcome assessment (detection bias) All outcomes	High risk	The researcher conducted the treatment and the measurements; our judgement given this factor is high risk
Incomplete outcome data (attrition bias) All outcomes	Low risk	All 21 participants completed the study
Selective reporting (reporting bias)	Low risk	All planned measurements appear to have been completed
Other bias	High risk	Not sufficiently powered

ITT: intention-to-treat.

RCT: randomised controlled trial.

TEWL: transepidermal water loss.

### Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
<a href="#">Ademola 2002</a>	Many participants < 60 years old and not possible to disaggregate data
<a href="#">Agero 2004</a>	Many participants < 60 years old and not possible to disaggregate data
<a href="#">Berth-Jones 1992</a>	Many participants < 60 years old and not possible to disaggregate data
<a href="#">Blaak 2015</a>	Intervention comparators are the same, except for different pH values, which is not standard practice and deviates from the criteria pre-specified in the review protocol
<a href="#">Brooks 2017</a>	Not an RCT
<a href="#">Danby 2014</a>	Not hospital or residential care based
<a href="#">de Paepe 2000</a>	Not hospital or residential care based
<a href="#">Draelos 2004</a>	Many participants < 60 years old and not possible to disaggregate data
<a href="#">Escudro 2013</a>	Not hospital or residential care based
<a href="#">Hoffman 2008</a>	Many participants < 60 years old and not possible to disaggregate data
<a href="#">Hollinworth 2008</a>	Not an RCT
<a href="#">Okada 2006</a>	Not an RCT
<a href="#">Scholermann 1998</a>	Not hospital or residential care based
<a href="#">Scholermann 1999</a>	Not hospital or residential care based
<a href="#">Scholermann 2001</a>	Not hospital or residential care based
<a href="#">Sheppard 2000</a>	Not an RCT
<a href="#">Viode 2005</a>	Not an RCT

RCT: randomised controlled trial.

### Characteristics of studies awaiting assessment *[ordered by study ID]*

#### **NCT02984527**

Methods	Randomised cross-over clinical trial where the effects of 2 interventions are compared in the same subject
Participants	Inclusion of 68 patients (18 years of age or older)  Inclusion criteria <ul style="list-style-type: none"> <li>• Patients who need intimate hygiene</li> <li>• Admitted for minimum 2 days</li> </ul>

**NCT02984527** (Continued)

- Understand oral information
- Able to sign written consent

## Exclusion criteria

- Diarrhoea
- Dementia
- Dying

Interventions	<p>Intervention 1: intimate hygiene with water and soap</p> <p>Intervention 2: intimate hygiene with pre-packaged disposable wet wipes</p> <p>Each individual will receive the 2 interventions in random order</p> <p>All participants will receive a sequence of the 2 different interventions with a washout period of 12 to 24 hours to avoid a cross-over effect</p>
Outcomes	<p>Differences in microbiological skin counts (delta values) before and after the 2 interventions and between interventions will be compared</p> <p>Data will be blinded during microbiological counts and statistical analyses</p>
Notes	<p>No results posted</p> <p>Trial register: NCT02984527</p>

**DATA AND ANALYSES**
**Comparison 1. Skin care regimen of moisturising body wash containing Shea butter and glycerin and a water-in-oil emulsion versus usual care**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Transepidermal water loss (temperature-adjusted g/m <sup>2</sup> /h)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Mid-volar forearm (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Lower leg (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Constratum corneum hydration (arbitrary units - 0 to 120) (higher readings indicate higher stratum corneum hydration)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Mid-volar forearm (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Lower leg (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Overall Dry Skin Score (5-point scale, higher scores = more dryness)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Right lower leg (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Left lower leg (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 Right forearm (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.4 Left forearm (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.5 Trunk (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Surface pH	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 Mid-volar forearm (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.2 Lower leg (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

**Analysis 1.1. Comparison 1 Skin care regimen of moisturising body wash containing Shea butter and glycerin and a water-in-oil emulsion versus usual care, Outcome 1 Transepidermal water loss (temperature-adjusted g/m<sup>2</sup>/h).**

Study or subgroup	Emollient		Usual care		Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)		
<b>1.1.1 Mid-volar forearm (day 56)</b>						
Hahnel 2017	36	9.9 (6.9)	32	12.6 (12.8)		-2.7[-7.67,2.27]
<b>1.1.2 Lower leg (day 56)</b>						
Hahnel 2017	36	9.8 (8.8)	31	9.7 (6.4)		0.1[-3.55,3.75]

Favours emollient    -10    -5    0    5    10    Favours usual care

**Analysis 1.2. Comparison 1 Skin care regimen of moisturising body wash containing Shea butter and glycerin and a water-in-oil emulsion versus usual care, Outcome 2 Constratum corneum hydration (arbitrary units - 0 to 120) (higher readings indicate higher stratum corneum hydration).**

Study or subgroup	Emollient		Usual care		Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)		
<b>1.2.1 Mid-volar forearm (day 56)</b>						
Hahnel 2017	39	42.3 (7.8)	35	41.4 (8.2)		0.9[-2.76,4.56]
<b>1.2.2 Lower leg (day 56)</b>						
Hahnel 2017	39	37.3 (9.8)	34	33.8 (8.3)		3.5[-0.65,7.65]

Favours usual care    -20    -10    0    10    20    Favours emollient

**Analysis 1.3. Comparison 1 Skin care regimen of moisturising body wash containing Shea butter and glycerin and a water-in-oil emulsion versus usual care, Outcome 3 Overall Dry Skin Score (5-point scale, higher scores = more dryness).**

Study or subgroup	Emollient		Usual care		Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)		
<b>1.3.1 Right lower leg (day 56 ± 4)</b>						
Hahnel 2017	39	1.7 (1.8)	35	1.9 (1.1)	-0.2	-0.2[-0.87,0.47]
<b>1.3.2 Left lower leg (day 56 ± 4)</b>						
Hahnel 2017	39	1.3 (1)	34	1.9 (1.1)	-0.6	-0.6[-1.08,-0.12]
<b>1.3.3 Right forearm (day 56 ± 4)</b>						
Hahnel 2017	40	1 (0.7)	36	1.6 (1.1)	-0.6	-0.6[-1.02,-0.18]
<b>1.3.4 Left forearm (day 56 ± 4)</b>						
Hahnel 2017	40	1.3 (1.7)	36	1.6 (1.1)	-0.3	-0.3[-0.94,0.34]
<b>1.3.5 Trunk (day 56 ± 4)</b>						
Hahnel 2017	40	0.4 (0.6)	35	0.8 (0.7)	-0.4	-0.4[-0.7,-0.1]

Favours emollient      -4      -2      0      2      4      Favours usual care

**Analysis 1.4. Comparison 1 Skin care regimen of moisturising body wash containing Shea butter and glycerin and a water-in-oil emulsion versus usual care, Outcome 4 Surface pH.**

Study or subgroup	Emollient		Usual care		Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)		
<b>1.4.1 Mid-volar forearm (day 56)</b>						
Hahnel 2017	39	5.2 (0.6)	35	5.2 (0.7)	0	0[-0.3,0.3]
<b>1.4.2 Lower leg (day 56)</b>						
Hahnel 2017	39	5.3 (0.6)	32	5.4 (0.6)	-0.1	-0.1[-0.38,0.18]

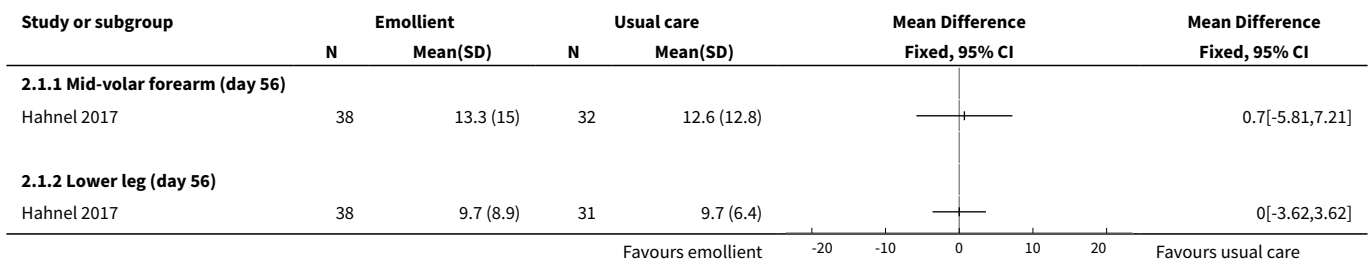
Favours emollient      -0.4      -0.2      0      0.2      0.4      Favours usual care

**Comparison 2. Skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea versus usual care**

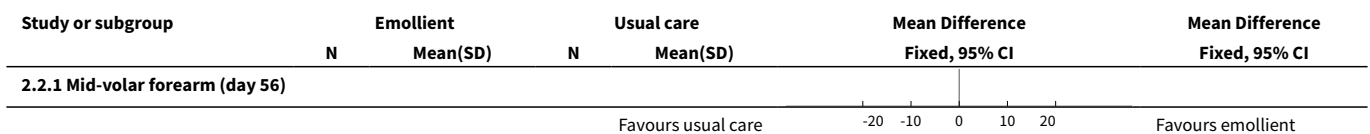
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Transepidermal water loss (temperature-adjusted g/m <sup>2</sup> /h)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Mid-volar forearm (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Lower leg (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Constratum corneum hydration (arbitrary units - 0 to 120)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
(higher readings indicate higher stratum corneum hydration)				
2.1 Mid-volar forearm (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Lower leg (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Overall Dry Skin Score (5-point scale, higher scores = more dryness)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Right lower leg (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Left lower leg (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 Right forearm (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.4 Left forearm (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.5 Trunk (day 56 ± 4)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Surface pH	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 Mid-volar forearm (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.2 Lower leg (day 56)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

**Analysis 2.1. Comparison 2 Skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea versus usual care, Outcome 1 Transepidermal water loss (temperature-adjusted g/m<sup>2</sup>/h).**



**Analysis 2.2. Comparison 2 Skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea versus usual care, Outcome 2 Constratum corneum hydration (arbitrary units - 0 to 120) (higher readings indicate higher stratum corneum hydration).**





Study or subgroup	Emollient		Usual care		Mean Difference	
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Mean Difference Fixed, 95% CI
Hahnel 2017	40	42.4 (9.6)	35	41.4 (8.2)		1[-3.03,5.03]
<b>2.2.2 Lower leg (day 56)</b>						
Hahnel 2017	40	32.7 (9.4)	34	33.8 (8.3)		-1.1[-5.13,2.93]

Favours usual care      -20 -10 0 10 20      Favours emollient

**Analysis 2.3. Comparison 2 Skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea versus usual care, Outcome 3 Overall Dry Skin Score (5-point scale, higher scores = more dryness).**

Study or subgroup	Emollient		Usual care		Mean Difference	
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Mean Difference Fixed, 95% CI
<b>2.3.1 Right lower leg (day 56 ± 4)</b>						
Hahnel 2017	41	1.5 (0.9)	35	1.9 (1.1)		-0.4[-0.86,0.06]
<b>2.3.2 Left lower leg (day 56 ± 4)</b>						
Hahnel 2017	41	1.4 (0.9)	34	1.9 (1.1)		-0.5[-0.96,-0.04]
<b>2.3.3 Right forearm (day 56 ± 4)</b>						
Hahnel 2017	41	1 (0.9)	36	1.6 (1.1)		-0.6[-1.05,-0.15]
<b>2.3.4 Left forearm (day 56 ± 4)</b>						
Hahnel 2017	41	1 (0.9)	36	1.6 (1.1)		-0.6[-1.05,-0.15]
<b>2.3.5 Trunk (day 56 ± 4)</b>						
Hahnel 2017	39	0.5 (0.6)	35	0.8 (0.7)		-0.3[-0.6,-0]

Favours emollient      -1 -0.5 0 0.5 1      Favours usual care

**Analysis 2.4. Comparison 2 Skin care regimen consisting of glycerin-containing body wash and a water-in-oil emulsion containing emollients and 4% urea versus usual care, Outcome 4 Surface pH.**

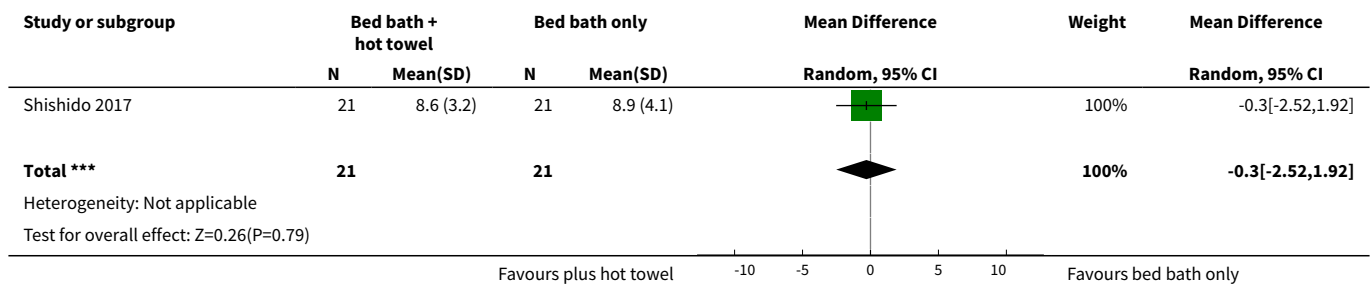
Study or subgroup	Emollient		Usual care		Mean Difference	
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Mean Difference Fixed, 95% CI
<b>2.4.1 Mid-volar forearm (day 56)</b>						
Hahnel 2017	40	5.4 (0.6)	35	5.2 (0.7)		0.2[-0.1,0.5]
<b>2.4.2 Lower leg (day 56)</b>						
Hahnel 2017	40	5.6 (0.6)	32	5.4 (0.6)		0.2[-0.08,0.48]

Favours emollient      -1 -0.5 0 0.5 1      Favours usual care

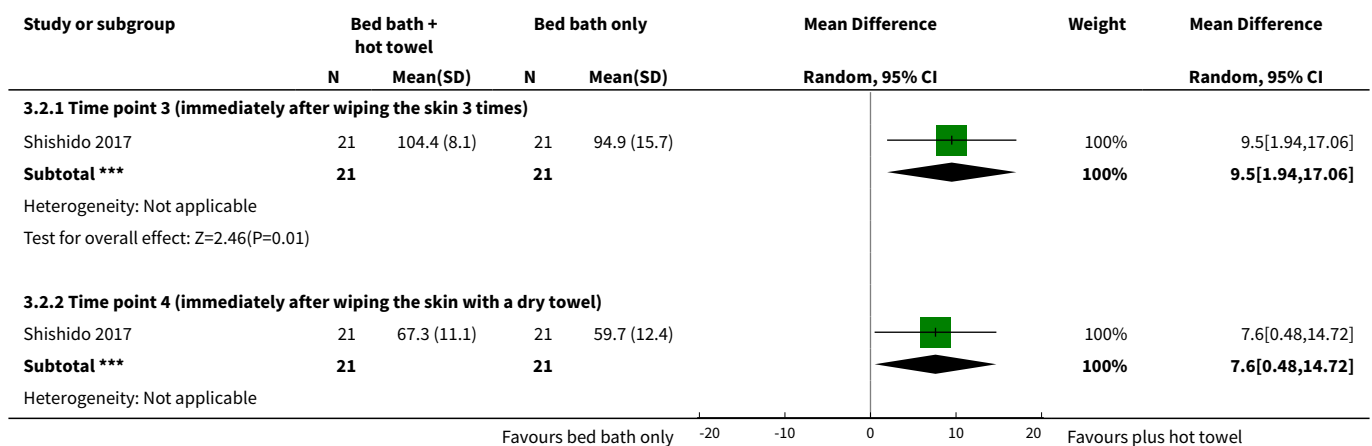
**Comparison 3. Bed bath with 10-second hot towel application versus bed bath only**

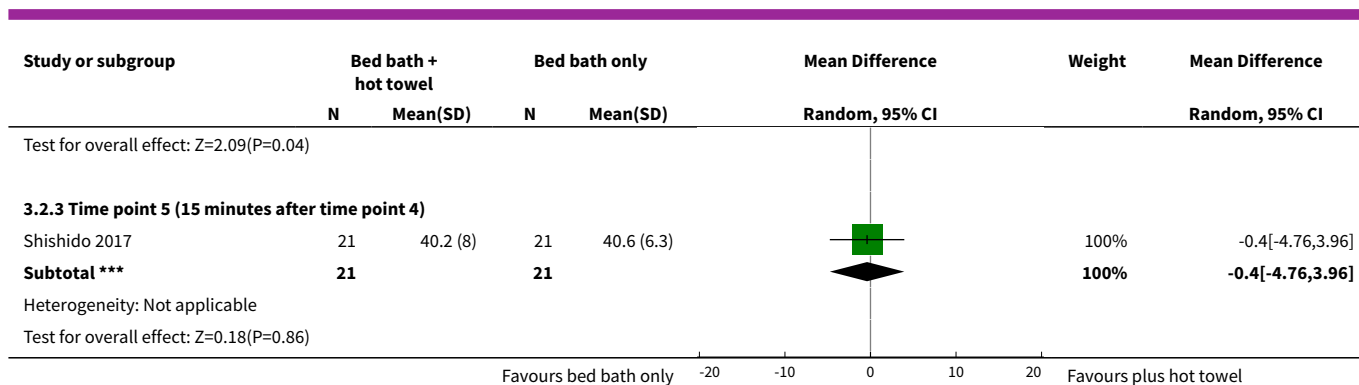
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Transepidermal water loss (g/m <sup>2</sup> /h) (time point 5 = 15 minutes after wiping with dry towel)	1	42	Mean Difference (IV, Random, 95% CI)	-0.30 [-2.52, 1.92]
2 Stratum corneum water content (arbitrary units - higher readings indicate higher stratum corneum hydration)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Time point 3 (immediately after wiping the skin 3 times)	1	42	Mean Difference (IV, Random, 95% CI)	9.5 [1.94, 17.06]
2.2 Time point 4 (immediately after wiping the skin with a dry towel)	1	42	Mean Difference (IV, Random, 95% CI)	7.60 [0.48, 14.72]
2.3 Time point 5 (15 minutes after time point 4)	1	42	Mean Difference (IV, Random, 95% CI)	-0.40 [-4.76, 3.96]

**Analysis 3.1. Comparison 3 Bed bath with 10-second hot towel application versus bed bath only, Outcome 1 Transepidermal water loss (g/m<sup>2</sup>/h) (time point 5 = 15 minutes after wiping with dry towel).**



**Analysis 3.2. Comparison 3 Bed bath with 10-second hot towel application versus bed bath only, Outcome 2 Stratum corneum water content (arbitrary units - higher readings indicate higher stratum corneum hydration).**





## ADDITIONAL TABLES

**Table 1. Glossary**

Term	Definition
<b>Emollient</b>	Products used to soften and add moisture to the skin
<b>Emulsify</b>	Make into or become an emulsion
<b>Emulsion</b>	A fine dispersion of minute droplets of 1 liquid into another, in which it is not soluble
<b>Humectant</b>	Substance that readily binds to water, and thereby helps keep skin moist
<b>Lauromacrogols</b>	Otherwise known as polidecanol, lauromacrogols are local anaesthetics that can relieve the itching associated with xerosis and atopic dermatitis
<b>Lipid lamellae synthesis</b>	The processing of lamellar lipids, which form the physical permeability barrier
<b>Physiological lipids</b>	Oils that can be metabolised by the human body, for example, the dietary fatty acid linoleic acid, found in vegetable oils such as sunflower oil. Non-physiological lipids, like white soft paraffin, are not metabolised by the body and therefore exert no physiological effect (either negative or positive)
<b>Protease</b>	A protein that cleaves (damages) other proteins, such as the proteins that help make up the skin barrier
<b>Stratum corneum</b>	The outermost layer of the skin consisting of keratinised cells
<b>Stratum corneum hydration</b>	This is routinely measured indirectly using probes that measure the electrical properties (capacitance or conductance) of the skin to estimate the water content. For example, hydrated skin displays an increased capacitance
<b>Surfactant</b>	A substance, for example, a detergent, that when added to a liquid increases its properties of spreading and wetting

**Table 2. Examples of intrinsic changes that occur in ageing skin**

Examples of intrinsic skin change	Effect on skin
Reduction in skin cell turnover (Finch 2003)	Papery appearance

**Table 2. Examples of intrinsic changes that occur in ageing skin** *(Continued)*

Skin gradually becomes more fragile as the epidermis thins and there is a reduction in integrity between epidermis and dermis ( <a href="#">Ward 2005</a> )	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 ( <a href="#">Ghadially 1995</a> ; <a href="#">Harding 2000</a> ; <a href="#">Rogers 1996</a> )	Decreased stratum corneum hydration and reduced integrity
Blood vessels become more fragile ( <a href="#">Fore 2006</a> ). Blood supply to the skin is reduced	Skin becomes more prone to bruising and damage
Collagen fibres that provide structural support stiffen ( <a href="#">Nazarko 2005</a> )  Elastic fibres thicken ( <a href="#">Finch 2003</a> )	Creases and wrinkles form  More prone to tearing and shearing
Production of sebum decreases ( <a href="#">Finch 2003</a> )	Skin becomes more dry  Vulnerable to splitting, cracking, and infection  Sensitivity to irritants increases
Sweat glands become smaller and secrete less sweat ( <a href="#">Ersser 2009</a> )	Skin becomes more dry  Less effective temperature control
Localised overproduction of melanin ( <a href="#">Finch 2003</a> )	Blotchiness and uneven pigmentation
Reduction in subcutaneous fat ( <a href="#">Burr 2005</a> )	Less protection and insulation
Reduction in sensory receptors ( <a href="#">Finch 2003</a> )	Less sensitivity, so more risk of inadvertent damage

The content of this table was previously published in [Coddell 2011](#).

**Table 3. Summary of intervention characteristics**

Author	Intervention	Intervention ingredients	Frequency	Duration	Body areas	Place of delivery	Mode of delivery	Outcomes measured (measurements)
Hopp 1974	Group B lotion	Oil and lotion: de-waxed, oil-soluble, keratin-moisturising fraction of lanolin, mineral oil, and non-ionic emulsifiers	Daily	12 days	Feet	2 nursing homes in the USA	Researcher	Foot condition (General Foot Condition Questionnaire): self-reported skin comfort measure)
	Group C water soak							
	Group D water soak + lotion							
	Group E oil soak							
	Group F oil soak + lotion							
Boccanfuso 1978	Washing with moisturising soap bar	"Special protein", a lanolin derivative, and glycerin, each participant twice daily under supervision	Twice daily	10 applications	1 leg	1 home for the elderly in the USA	Unclear	Skin dryness on legs (xerosis severity (dryness) score of 0 (no flaking) to 5 (severe flaking)) adapted from Rieger 1974: no evidence of validity testing found
Carville 2014	'Usual' care + emollient	Commercially available, standardised pH (5-6) neutral, perfume-free moisturiser (Abena)	Intervention: twice daily	6 months	Extremities	14 aged care facilities in Australia	Staff following education or residents	Skin tears: number of skin tears/residents occupied bed-days) × 1000 (STAR Skin Tear Classification, a validated tool that measures tears according to characteristics such as loss of tissue and presence



**Table 3. Summary of intervention characteristics** (Continued)

								of haematoma) (Carville 2007)
Gillis 2016	Usual care + “wash gloves”	Aqua, propylene glycol, coco-glucoside, phenoxyethanol, parfum, benzoic acid, polyamino-propyl biguanide, octyldodecanol, aloe barbadensis, glycine soja oil, dehydroacetic acid, sodium lauroamphoacetate, <i>Calendula officinalis</i> extract, <i>Tilia cordata</i> extract, <i>Melissa officinalis</i> extract, <i>Hamamelis virginiana</i> extract, <i>Echinacea purpurea</i> extract, <i>Chamomilla recutita</i> extract, <i>Centella asiatica</i> extract, aloe barbadensis gel, tocopherol	Daily	12 weeks	Body	6 wards within 2 nursing homes in Flanders (Northern Belgium)	Carers	Stratum corneum hydration was measured using a MoistureMeter SC at 3 skin sites (hand, leg, and cheek)
Hahnel 2017	Group 1: structured skin care regimen  Group 2: structured skin care regimen	Group 1: moisturising body wash containing Shea butter and glycerin, moisturising leave-on hydrophilic water-in-oil emulsion lotion  Group 2: glycerin-containing body wash, a water-in-oil emulsion containing emollients and 4% urea	Body wash: daily  Lotion: twice daily	2 months	Body wash: not stated  Lotion: arms, legs, and trunk	10 institutional long-term-care facilities in Germany	Participants and/or nurses following training	Skin dryness (validated Overall Dry Skin Score (Serup 1995) of 0 to 4 allocated to scaling, roughness, redness, and cracks/fissures, allowing a score of 1 to 16). Stratum corneum hydration (Corneometer CM 825). Transepidermal water loss (Tewameter TM 300). Skin surface pH (Skin-pH-Meter1 PH 905). Skin surface temperature (SkinThermometer ST 500)
Shishido 2017	A hot towel for 10 seconds after a usual care bed bath	Cotton wash cloth heated to 50°C	Once	Once only	Forearm	2 long-term healthcare facilities in Japan	Unclear	Stratum corneum hydration was measured using a corneometer (CM825 manufactured by Courage and Khazaka, Cologne, Ger-



many), TEWL using Tewameter (TM300 manufactured by Courage and Khazaka), and skin surface temperature using Thermography (R300 manufactured by NEC of Tokyo, Japan)

**Table 3. Summary of intervention characteristics** (Continued)

## APPENDICES

### Appendix 1. Cochrane Skin Group Specialised Register/CRS search strategy

((Bath\* or "strip wash\*" or shower\* or towel\* or wash\* or soap\* or clean\* or wipe\* or emollient\* or moisturis\* or moisturiz\* or lotion\* or cream\* or ointment\* or water or hygien\* or "skin cream" or "skin care") and ("skin integrity" or (skin near2 dry\*) or xeroderma or xerodermia or scaling or "skin cracking" or xerosis or fissure\* or pruritus or itch\*) and (elderly or geriatric\* or older or aged)):ti,ab

### Appendix 2. CENTRAL (Cochrane Library) search strategy

#1 (Bath\* or "strip wash\*" or shower\* or towel\* or wash\* or soap\* or clean\* or wipe\* or emollient\* or moisturis\* or moisturiz\* or lotion\* or cream\* or ointment\* or water or hygien\* or "skin cream" or "skin care"):ti,ab,kw  
 #2 MeSH descriptor: [Baths] explode all trees  
 #3 MeSH descriptor: [Soaps] explode all trees  
 #4 MeSH descriptor: [Emollients] explode all trees  
 #5 MeSH descriptor: [Water] explode all trees  
 #6 MeSH descriptor: [Hygiene] explode all trees  
 #7 MeSH descriptor: [Skin Cream] explode all trees  
 #8 MeSH descriptor: [Skin Care] explode all trees  
 #9 {or #1-#8}  
 #10 ("skin integrity" or (skin near/3 dry\*) or xeroderma or xerodermia or scaling or "skin cracking" or xerosis or fissure\* or pruritus or itch\*):ti,ab,kw  
 #11 MeSH descriptor: [Pruritus] explode all trees  
 #12 MeSH descriptor: [Skin] this term only  
 #13 {or #10-#12}  
 #14 (elderly or geriatric\* or older):ti,ab,kw  
 #15 MeSH descriptor: [Aged] explode all trees  
 #16 {or #14-#15}  
 #17 #9 and #13 and #16

### Appendix 3. 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. (moisturis\$ 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 or xeroderma or xerodermia).ti,ab.
28. (fissure\$ or scaling or "skin cracking").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

[Lines 39-48: Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision)]

#### Appendix 4. Embase (Ovid) search strategy

1. (Bath\$3 or "strip wash\$3" or shower\$ or towel\$ or wash\$3 or soap\$ or clean\$4 or cleanliness or wipe\$1 or emollient\$ or moisturis\$ or moisturiz\$ or lotion\$ or cream\$ or ointment\$ or water or hygien\$ or "skin cream" or "skin care").ti,ab.
2. bath/
3. hygiene/
4. soap/
5. emollient agent/
6. ointment/
7. water/
8. skin cream/
9. skin care/
10. or/1-9
11. skin integrity.ti,ab.
12. skin.ti,ab.
13. \*skin/
14. (xerosis or xeroderma or xerodermia).ti,ab.
15. xerosis/
16. xeroderma/
17. (fissure\$ or scaling or "skin cracking").ti,ab.
18. skin fissure/
19. pruritus/ or skin pruritus/
20. pruritus.ti,ab.
21. itch\$.ti,ab.
22. dry skin/
23. (skin adj3 dry\$).ti,ab.
24. or/11-23
25. aged/
26. (aged or elderly or geriatric).ti,ab.
27. 25 or 26
28. (singl\$ adj blind).ti,ab.
29. crossover procedure.sh.
30. double-blind procedure.sh.
31. single-blind procedure.sh.
32. (crossover\$ or cross over\$).tw.
33. placebo\$.tw.
34. (doubl\$ adj blind\$).tw.
35. allocat\$.tw.
36. trial.ti.

37. randomized controlled trial.sh.
38. random\$.tw.
39. or/28-38
40. exp animal/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
41. human/ or normal human/
42. 40 and 41
43. 40 not 42
44. 39 not 43
45. 10 and 24 and 27 and 44

#### Appendix 5. CINAHL (EBSCO) search strategy

- S1 (MH "Clinical Trials+")  
 S2 PT clinical trial  
 S3 TX (clinic\* n1 trial\*)  
 S4 (MH "Random Assignment")  
 S5 TX random\* allocat\*  
 S6 TX placebo\*  
 S7 (MH "Placebos")  
 S8 (MH "Quantitative Studies")  
 S9 TX allocat\* random\*  
 S10 "randomi#ed control\* trial\*"  
 S11 TX ( (singl\* n1 blind\*) or (singl\* n1 mask\*) ) or TX ( (doubl\* n1 blind\*) or (doubl\* n1 mask\*) ) or TX ( (tripl\* n1 blind\*) or (tripl\* n1 mask\*) ) or TX ( (trebl\* n1 blind\*) or (trebl\* n1 mask\*) )  
 S12 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11  
 S13 TI ( (Bath\* or "strip wash\*" or shower\* or towel\* or wash\* or soap\* or clean\* or wipe\* or emollient\* or moisturis\* or moisturiz\* or lotion\* or cream\* or ointment\* or water or hygien\* or "skin cream" or "skin care" ) ) OR AB ( (Bath\* or "strip wash\*" or shower\* or towel\* or wash\* or soap\* or clean\* or wipe\* or emollient\* or moisturis\* or moisturiz\* or lotion\* or cream\* or ointment\* or water or hygien\* or "skin cream" or "skin care" ) )  
 S14 TI ( ( "skin integrity" or (skin n2 dry\*) or xeroderma or xerodermia or scaling or "skin cracking" or xerosis or fissure\* or pruritus or itch\* ) ) OR AB ( ( "skin integrity" or (skin n2 dry\*) or xeroderma or xerodermia or scaling or "skin cracking" or xerosis or fissure\* or pruritus or itch\* ) )  
 S15 TI ( (elderly or geriatric\* or older or aged) ) OR AB ( (elderly or geriatric\* or older or aged) )  
 S16 S12 AND S13 AND S14 AND S15

[Lines S1-S12: the SIGN filter for RCTs in CINAHL via EBSCO].

#### Appendix 6. ISRCTN registry search strategy

Skin and connective tissue diseases

Skin

#### Appendix 7. Clinical trials.gov search strategy

Skin

#### Appendix 8. Australian New Zealand Clinical Trials Registry search strategy

Emollient

Skin hygiene

Skin barrier

#### Appendix 9. WHO International Clinical Trials Registry search strategy

Skin and emollient

Skin and hygiene

#### Appendix 10. EU Clinical Trials Register search strategy

Skin and elderly

### CONTRIBUTIONS OF AUTHORS

FC was the contact person with the editorial base.

**Hygiene and emollient interventions for maintaining skin integrity in older people in hospital and residential care settings (Review)**

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FC co-ordinated contributions from co-authors.  
FC and JD wrote the final draft of the review.  
FC, JD, and YJ screened papers against eligibility criteria.  
FC obtained data on ongoing and unpublished studies.  
FC, YJ, and JD appraised the quality of papers.  
FC, YJ, and JD extracted data for the review and sought additional information about papers.  
FC entered data into RevMan.  
JD analysed and interpreted data.  
FC, JD, SL, and SE worked on the methods sections.  
SD and FC drafted the clinical sections of the background and responded to the clinical comments of the referees.  
JD and FC responded to the methods and statistics comments of the referees.  
AR was the consumer co-author and checked the review for readability and clarity, as well as to ensure that outcomes are relevant to consumers.  
FC is the guarantor of the update.

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## DECLARATIONS OF INTEREST

Fiona Cowdell: none known.

Yuri Jadotte: none known.

Steven Ersser: none known.

Simon Danby: my institution has received research funding from Almirall, Hyphens Pharma, Johnson & Johnson, Leo Pharma, Perrigo Company, and L'Oreal, which manufacture topical treatments for skin conditions; I have received honoraria from Astellas and Almirall for speaking/presenting at conferences; and consultancy fees from Astellas Pharma Europe and Almirall for services as a scientific writer or for presenting study results relating to emollient use in older people (posters and lectures) at conferences and other meetings.

Sandra Lawton: has received money for a lecture from Thornton & Ross Ltd. 2016 and for review of educational slides for Bayer 2016.

Amanda Roberts: none known.

Judith Dyson: none known.

Jan Kottner, clinical referee, is an author of the included study [Hahnel 2017](#).

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- No sources of support supplied

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## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We used GRADEpro software to construct a 'Summary of findings' table, but none of the included studies considered erythema or clinical score of itch.

We excluded a number of studies because many participants were younger than 60 years of age; we had not planned this in the protocol, but we made this decision because it was not possible to disaggregate the data.

**Methods > Primary outcome measures:** we removed "(dryness or eczema on the Skin Condition Form as assessed by an observer)" from our outcome 'Frequency of skin damage' and added (for example, (a) complete loss of integrity such as tears or ulceration, or (b) partial loss of integrity such as fissuring, to clarify and avoid overlap with secondary outcome four - 'clinical score of dryness'.

**Searching other resources > Unpublished literature:** in the protocol, we planned to investigate unpublished and grey literature via correspondence with authors and major pharmaceutical companies. We did not do this because the authors of this review agreed that such an undertaking was unlikely to yield results that would alter our conclusions. This decision was made by team consensus, based on professional knowledge, taking into account the publication of a study that had been in progress at the time the protocol for this title was written.

**Methods > Data collection and analysis > Data extraction and management:** we used Grading of Recommendations Assessment, Development and Evaluation (GRADE) to assess the quality of evidence for our 'Summary of findings' table and created the table using GRADEpro (Balslem 2011; Guyatt 2011).

**Methods > Data collection and analysis > Measures of treatment effect:** if we could directly combine the studies included in the review, we planned to use the meta-analysis techniques discussed in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We intended to use odds ratios as measures of treatment effect for dichotomous outcome measures. We intended 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. We did not undertake these plans because either measures of treatment effect precision or study outcome definitions were unavailable for all included studies.

**Methods > Data collection and analysis > Unit of analysis issues:** if studies included a within-patient trial (e.g. different interventions used for different parts of the body), we had planned to 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 had planned to obtain measures of treatment effect based on a paired t-test. We did not plan to combine these results with results from parallel-group trials. We might have combined results from cluster-randomised studies in a meta-analysis if cluster-randomised studies were included. We did not plan to combine results from cluster-randomised studies with results from parallel-group trials in case such studies differ in other ways apart from study design. We did not undertake any of these plans for the reasons given in the previous paragraph for the included studies that used within-patient and cluster-randomised studies.

**Methods > Data collection and analysis > Dealing with missing data:** if necessary, we planned to undertake a sensitivity analysis to examine the impact on the overall treatment effect when attempts to obtain further details from the original study authors were unsuccessful. This would have involved conducting a meta-analysis twice - first with all studies included using an available case analysis, and then with omission of studies with higher levels of potential bias, including attrition bias arising from missing data. We did not undertake this plan because measures of treatment precision or study outcome definitions were unavailable in the first place.

**Methods > Data collection and analysis > Assessment of heterogeneity:** assuming that outcome measures from included studies were potentially comparable in the first place (please see the [Data synthesis](#) section), we planned to 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 intended to assess whether this was due to a single 'outlier' study. If this was the case, we would have performed and reported meta-analyses both with and without this study. If there were no obvious outlying studies, we would have tried to establish the reasons for heterogeneity and come to a decision on the viability of a meta-analysis. We did not undertake these plans because measures of treatment precision or study outcome definitions were unavailable in the first place.

**Methods > Data collection and analysis > Assessment of reporting biases:** we intended to assess publication bias using funnel plots if we had included at least 10 studies (following the recommendation in Chapter 10 of Higgins 2011) and if a meta-analysis had been feasible. If asymmetry was found, we would have considered publication bias as one possible cause. We did not undertake these plans because measures of treatment precision or study outcome definitions were unavailable in the first place.

**Methods > Data collection and analysis > Data synthesis:** if there had not been too much diversity between studies, we would have compared outcome measures across studies for each outcome of interest. We planned to use the meta-analysis techniques in Chapter 9 of Higgins 2011 for combining outcome measures on different scales, provided there was no evidence that some study populations were genuinely more variable than others. We would then have tested for heterogeneity of the intervention effect as described in the [Assessment of heterogeneity](#) section. If studies were pooled, we planned to use a fixed-effect meta-analysis. We did not undertake these plans because measures of treatment precision or study outcome definitions were unavailable in the first place.

**Methods > Data collection and analysis > Data synthesis:** when results were estimated for individual studies with small numbers of outcomes (< 10 in total), or when the total sample size is less than 30 participants, we intended to report the proportion of dichotomous outcomes in each treatment group together with a P value from Fisher's exact test. We did not do this because no study fulfilled these criteria.

We have provided a two-part narrative synthesis, as quantitative synthesis of the included studies would not be appropriate or meaningful due to heterogeneity in intervention ingredients, body areas treated, and outcome measures.

**Methods > Data collection and analysis > Subgroup analysis and investigation of heterogeneity:** we planned to assess statistical heterogeneity using the  $I^2$  statistic, but we did not do this because measures of treatment precision or study outcome definitions were unavailable in the first place.

**Methods > Data collection and analysis > Sensitivity analysis:** in the event that we had decided to use a meta-analysis, and that some studies were found to have higher levels of potential bias when the 'Risk of bias' checklist was applied, we would have performed a sensitivity analysis. This would have involved conducting a meta-analysis twice - first with all studies included, and then with omission of 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. We did not undertake these plans because measures of treatment precision or study outcome definitions were unavailable in the first place.