

# Interventions for preventing and treating incontinence-associated dermatitis in adults

## Review information

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## Abstract

### Background

Incontinence-associated dermatitis (IAD) is one of the most common skin problems in adults who are incontinent for urine, stool or both. [In practice, products and procedures are the same for both prevention and treatment of IAD.](#)

### Objectives

To assess the effectiveness of products and procedures to prevent and treat IAD. More specifically, to compare different topical skin care products, structured and unstructured skin care procedures and different methods and frequencies of application of topical skin care products.

### Search methods

We developed a search filter [which was used to search electronic databases in](#) ~~and searched electronic databases in~~ two steps. In a first step, we searched the Cochrane Incontinence Group Specialised Trials Register (searched 29 April 2015). In a second step, we searched other electronic databases: Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 4), MEDLINE (January 1946 to May Week 3 2015), MEDLINE In-Process (inception to 26 May 2015), Cumulative Index for Nursing and Allied Health (CINAHL; December 1981 to 28 May 2015), Web of Science (WoS; inception to 28 May 2015). Additionally, we handsearched conference proceedings (to June 2015) [and](#); the reference lists of relevant articles, and we contacted authors and experts in the field.

### Selection criteria

We ~~included~~ [selected](#) randomised ~~as well as~~ [and](#) quasi-randomised trials, [performed in any health care setting, which included participants over 18 years of age with or without IAD. We included trials comparing the \(cost\) effectiveness of topical skin care products such as skin cleansers, moisturisers, and skin protectants of different compositions and skin care procedures aiming to prevent and treat IAD.](#)

### Data collection and analysis

Two review authors independently screened titles, abstracts and full-texts, extracted data, and assessed [the](#) risk of bias of the included trials.

### Main results

Thirteen trials, including 1292 participants, were included in a qualitative synthesis. Participants were incontinent for urine, stool or both, and were residents in a nursing home or hospitalised.

[Eleven trials had a small sample size and short follow-up periods. Blinding of outcome-assessment was not performed in nine trials. The data were not suitable for meta-analysis due to heterogeneity in participant population, skin care products, skin care procedures, outcomes, and measurement tools.](#)

Nine trials compared different topical skin care products, including a combination of products. Two trials tested a structured skin care procedure. One trial compared topical skin care products alongside frequencies of

application. One trial compared frequencies of application of topical skin care products.

We found evidence in two trials, [being](#) of low ~~to~~and moderate quality, that soap and water performed [poorly](#) in the prevention and treatment of IAD. The first trial ~~determined~~[indicated](#) that the use of a skin cleanser [can/might](#) be more effective than the use of soap and water. The second trial ~~determined~~[indicated](#) that a structured skin care procedure ~~using~~[being](#) a washcloth with cleansing, moisturising, and protecting properties [can/might](#) be more effective than soap and water. Findings from the other trials, all [being](#) of low to very low quality, suggest that applying a leave-on product (moisturiser, skin protectant, or [a](#) combination) [is/might](#) more effective than withholding a leave-on product.

~~Eleven trials had a small sample size and short follow-up periods. Blinding of outcome assessment was not performed in at least nine trials. The data were not suitable for meta-analysis due to heterogeneity in participant population, skin care products, skin care procedures, outcomes and tools used to measure the outcomes.~~

## Authors' conclusions

Very limited evidence exists on the effects of interventions for preventing and treating IAD in adults. Soap and water performed [poorly](#) in the prevention and treatment of IAD. Application of leave-on products (moisturisers, skin protectants, or a combination) seems to be more effective than withholding these products. High quality confirmatory trials using [standardized](#), and comparable prevention and treatment regimens in different settings/regions are required. Furthermore, to increase the comparability of trial results, we recommend the development of a core outcome-set, including validated measurement tools. [The evidence in this review is current up to 27 May 2015.](#)

## Plain language summary

### Interventions for preventing and treating incontinence-associated dermatitis in adults

#### Background

Incontinence-associated dermatitis (IAD) is an inflammation of the skin due to contact with urine or stool. IAD occurs in people with involuntary loss of urine or stool (incontinence). The main symptom of IAD is skin redness. In addition, bullae, skin lesions and skin infection may occur. IAD affects one to five in ten incontinent adults and is a risk factor for pressure related skin problems. To prevent and treat IAD, skin cleansing and skin care products are recommended. Many skin care products and procedures are available. The skin care products can be divided into cleansers, moisturisers and protectants which may be combined (for example a cleanser/moisturiser). [In practice, products and procedures are the same for both prevention and treatment.](#)

#### Review question

This review clarified the effect of various skin care products and procedures to prevent and treat IAD.

#### Study characteristics

We included randomised controlled trials which compared skin care products, procedures, methods for using skin care products and frequencies of using a skin care product. [The participants had to be over 18 years of age.](#)

#### Key results

We found thirteen, mostly small, trials, including 1292 participants. All participants were incontinent for urine, stool or both and lived in nursing homes or were hospitalised. The trials tested skin care products, procedures and frequencies of using a skin care product.

Two trials showed that soap and water performed [poorly](#) in the prevention and treatment of IAD. A skin

cleanser [or a washcloth with cleansing, moisturising and protecting properties](#) may be more effective than soap and water. The findings from the other trials suggest that using a skin care product is more effective than withholding a skin care product. We found no evidence that one skin care product performed better than another.

### Quality of evidence

The quality of the evidence was low. Eleven trials included less participants and were of short duration. In all of the trials, important potential bias was present.

### Authors conclusions

The trials included in this review tested skin care products, procedures and frequencies of using a skin care product. Very limited evidence exists on the effects of interventions for preventing and treating IAD in adults. Larger, long-term and well performed trials are required. Furthermore, we recommend the development of list of items which are important for patients and researchers to study. This list should include well developed tools to measure the items in order to obtain accurate results.

## Background

### Description of the condition

Incontinence is defined as the complaint of any involuntary loss of urine (urine incontinence) or faecal material (faecal incontinence) or both (double incontinence) ([Abrams 2009](#)). Incontinence is a widespread problem in all healthcare settings ([Du Moulin 2008](#); [Macmillan 2004](#)). Figures from studies on the prevalence of urinary/faecal incontinence vary, mainly attributable to the population type and the study protocol used. With prevalence estimates between 10% and 15% for faecal incontinence measured in community-dwelling adults ([Macmillan 2004](#); [Shamliyan 2007](#)) and up to 46% for urinary incontinence measured in older, home-care patients ([Du Moulin 2008](#)), it is clear that incontinence care is an important task for clinicians, patients, and their carers. Incontinence can lead to numerous complications. One of the most common complications is perineal skin breakdown ([Gray 2010](#); [Langemo 2011](#)).

### *Incontinence-associated dermatitis*

We can define incontinence-associated dermatitis (IAD) as erythema and oedema of the surface of the skin, sometimes accompanied by bullae with serous exudates, erosion, or secondary cutaneous infection. Skin exposed to moisture, such as faecal or urinary incontinence, is susceptible to the development of IAD. Gray defined IAD as a skin inflammation manifested as redness with or without blistering, erosion, or loss of the skin barrier function that occurs as a consequence of chronic or repeated exposure of the skin to urine or faecal matter ([Gray 2007](#)). IAD is the result of top-down damage to the skin due to:

- tissue intolerance (e.g. age, nutrition);
- an affected perineal environment (e.g. due to incontinence); and
- problems with toileting ability (e.g. restraints) ([Beeckman 2009](#)).

The most important etiologic factors are urinary, faecal and double incontinence ([Beeckman 2014](#)). Faecal incontinence has been identified as a particularly high risk factor for the development of IAD with liquid faecal matter as the most severe irritant ([Beeckman 2009](#)).

Traditionally, IAD has received little attention as a distinct skin disorder, and it is regularly confused with Category/Stage I and II pressure ulcers ([Beeckman 2010](#); [Beeckman 2014](#)). The clinical presentation of IAD ranges from erythema (with or without loss of skin) to cutaneous infections (such as candidiasis) ([Beeckman 2007](#)). IAD is often associated with redness, rash, or vesiculation ([Gray 2007](#)). Although the lesions are superficial, they are likely to become slightly deeper when an infection occurs. In contrast, the clinical signs of

pressure ulcers range from non-blanchable erythema of the intact skin, over partial/full thickness skin loss, to tissue destruction involving skin, subcutaneous fat, muscle, and bone ([NPUAP 2014](#)). A recent systematic review and meta-analysis by [Beeckman 2014](#) confirmed incontinence (and moisture in general) and IAD as an important risk factor for pressure ulcer development ([Beeckman 2014](#)).

## Prevalence

Studies report prevalence figures of IAD between 5.6% to 50.0%, with incidence rates between 3.4% and 25.0%, depending on the type of setting and population studied ([Gray 2007](#)). Most epidemiological studies were performed in small-sample, single-centre, and long-term care settings ([Gray 2012](#)). A study on the prevalence of IAD among hospitalised acute-care patients in the United States (n = 976) reported a prevalence of 27% ([Junkin 2007](#)). A study using a large sample (n = 3713) of incontinent participants reported an overall IAD prevalence across different healthcare settings in two European countries of 6.1% ([Kottner 2014](#)). Approximately one-third of people with faecal incontinence develop IAD ([Gray 2002](#)). Incontinence, and subsequent skin breakdown, have a considerable effect on patients' physical and psychological well-being ([Newman 2007](#); [Sibbald 2003](#)).

## Etiology

The etiology of IAD is complex and related to both chemical and physical irritation of the skin ([Beeckman 2009](#)). [Ananthapadmanabhan 2004](#) demonstrated that a rise in pH (caused by urine and faeces) increases stratum corneum swelling and alterations in lipid rigidity, thus increasing the permeability of the skin and reducing the barrier function. Furthermore, a more alkaline pH increases the risk of bacterial colonization and thus cutaneous infections. Friction (physical irritation) increases when the skin rubs over clothing, diapers/pads, and bed or chair surfaces. The combination of chemical and physical irritation results in a weakened skin. If these mechanisms affect the integrity of the skin recurrently, IAD and further skin breakdown are likely to develop ([Beeckman 2009](#)).

To date, there has been a lack of rigorously performed research addressing the effectiveness of different skin care regimens to prevent or treat IAD. A number of studies compared the use and effects of different types of skin regimens, but design weaknesses seem to be common. Tentative evidence indicates that key prevention recommendations include structured skin care regimens including gentle cleansing, moisturisation, and the application of skin protectants or moisture barriers.

## Description of the intervention

Current prevention of IAD consists of skin care interventions such as skin cleansing, moisturisation/skin conditioning, and the application of skin protectants/barriers. Treatment includes protecting the skin from further exposure to irritants, establishing a healing environment, and eradicating skin infections. A plethora of over-the-counter and prescribed products for cleansing, moisturisation, and protecting (creams, ointments, pastes, film layers, etc.) as well as procedures to apply the products (for example frequency and method of application) are currently available. [The same products are used for patients with and without IAD. Topical antibiotics and antimycotics are additionally used to eradicate skin infections.](#)

## How the intervention might work

We considered three main interventions (cleansing, moisturising, protection) using topical skin care products in this review. We also investigated different procedures for their use, such as frequency or method of application.

### **Cleansing**

Skin cleansing aims to remove dirt, debris, and microorganisms on the skin surface, usually using water alone or in combination with skin cleansers.

## **Moisturising**

Skin moisturisation aims to repair or augment the skin's barrier, retain and/or increase its water content, reduce transepidermal water loss, and restore or improve the intercellular lipid structure.

## **Protectants and barriers**

The primary purpose of a skin protectant is to prevent skin breakdown by providing an impermeable or semipermeable barrier on the skin, thus preventing or reducing the penetration of water and chemical and biological irritants found in stool and urine.

## **Why it is important to do this review**

A wide range of topical skin care products and procedures are currently used in practice. Despite their widespread use, little is known about their efficacy and effectiveness. We conducted this review to clarify the effects of various products and skin care protocols to prevent and treat IAD in adults.

## **Objectives**

The objective of this review was to assess the effectiveness of various products and procedures to prevent and treat incontinence-associated dermatitis in adults.

## **Methods**

### **Criteria for considering studies for this review**

#### **Types of studies**

We included all randomised controlled trials and quasi-randomised trials if one arm of the trial included a structured and well-defined procedure (including a standard frequency, method, and product selection) or a skin care product used to prevent or treat incontinence-associated dermatitis (IAD). We compared these with other structured skin care procedures or unstructured (not standardised) procedures or other products, methods, or frequencies used to prevent or treat IAD.

#### **Types of participants**

Studies involving male and/or female participants over 18 years of age, in any healthcare setting, with or without IAD (defined as erythema and oedema of the surface of the skin, sometimes accompanied by bullae with serous exudates, erosion, or secondary cutaneous infection) were eligible for inclusion.

#### **Types of interventions**

We included trials of topical skin care products such as skin cleansers, moisturisers, and skin protectants of different compositions and skin care procedures aiming to prevent or treat IAD in this review. We examined the following comparisons:

1. Any topical skin care product versus another topical skin care product

Subgroups:

- Cleansing products
- Moisturising products
- Protectants and barriers

2. Any skin care procedure (method or frequency of application) versus any unstructured skin care procedure

3. Any method of application of a topical skin care product versus another method of application of the topical skin care product

4. Any frequency of application of a topical skin care product versus another frequency of application of the topical skin care product

## Types of outcome measures

### Primary outcomes

1. Number of participants with IAD (residual, i.e. not healed)
2. Number of participants with IAD (new) (only suitable to evaluate interventions for preventing IAD)
3. Number of participants not satisfied with treatment

### Secondary outcomes

1. Participants' observations
  - a. Number of participants with pain due to IAD
  - b. Number of participants with pain due to skin care product or procedure
2. Quantification of symptoms (objective measures)
  - a. Surface affected by IAD (measurement of size of lesion)
3. Clinician's observations
  - a. Number of participants with IAD not improved (only suitable to evaluate interventions for treating IAD)
  - b. Number of participants not complying/discontinuing treatment (acceptability and tolerance)
4. Quality of life
  - a. Condition-specific
  - b. Generic (e.g. SF-36, EQ-5D, Manchester Short Assessment of Quality of Life)
  - c. Psycho-social
5. Socioeconomic measures
  - a. Cost of products
  - b. Staff time
  - c. Cost-effectiveness
6. Adverse effects (of the interventions)
  - a. Adverse reaction due to the skin care product or procedure, e.g. skin irritation, rash, itching, allergic reaction
  - b. Normal flora disruption
  - c. Toxicity
  - d. Treatment-related pain/discomfort
7. Other outcomes (non-pre-specified outcomes judged important when performing the review)

## Quality of evidence Potential participant-important outcomes

We used the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system to assessed the quality of the evidence by using the software program GRADEpro. ~~We assessed the relevance of the effect of the interventions based on a judgment of each outcome separately using GRADEpro. GRADE allowed us to assess the quality of the body of evidence by taking into account five considerations: study limitations, consistency of effect, imprecision, indirectness, and publication bias. The review authors classified primary and secondary outcomes, as defined above, as 'critical', 'important', or 'not important' for decision making from the participant's perspective.~~ The GRADE working group strongly recommends including up to seven potentially participant-important outcomes in a systematic review ([Guyatt 2011](#)). Based on discussion within the research group, the review authors selected following ~~In this systematic review~~ potential

participant-important outcomes ~~were~~:

- Number of participants with IAD (residual)
- Number of participants with IAD (new)
- Number of participants not satisfied with treatment
- Number of participants with pain due to IAD
- Number of participants with pain due to skin care product or procedure
- Adverse reaction due to the skin care product or procedure, e.g. skin irritation, rash, itching, allergic reaction
- Cost-effectiveness

## Search methods for identification of studies

We undertook a two-step search strategy to identify relevant literature. Firstly, we searched electronic databases. Secondly, we searched other sources, such as conference proceedings. We imposed no restrictions, such as language or publication status, on the searches.

### Electronic searches

This review drew on the search strategy developed for the Cochrane Incontinence Group. We identified relevant trials from the Cochrane Incontinence Group Specialised Trials Register. For more details of the search methods used to build the Specialised Register, please see the Group's [module](#) in the Cochrane Library. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE in process, ClinicalTrials.gov, and WHO ICTRP, and handsearching of journals and conference proceedings. Many of the trials in the Cochrane Incontinence Group Specialised Register are also contained in CENTRAL.

The terms used to search the Cochrane Incontinence Group Specialised Register are given in [Appendix 1](#). The date of the last search was 29 April 2015.

Additionally, as the condition can be very poorly described, especially in the older literature, we searched the following electronic databases:

- CENTRAL on OvidSP 2015, issue 4 was searched on 27 May 2015. The search strategy is given in [Appendix 2](#).
- MEDLINE on OvidSP (covering from January 1946 to May Week 3 2015) was searched on 27 May 2015. The search strategy is given in [Appendix 2](#).
- MEDLINE in process on OvidSP (covering 26 May 2015) was searched on 27 May 2015. The search strategy is given in [Appendix 2](#).
- Cumulative Index for Nursing and Allied Health (CINAHL), was searched through the EBSCO Interface, from inception (December 1981) to the most recent version available (20150527 - entry date) on 28 May 2015. The search strategy is given in [Appendix 3](#).
- Web of Science (WoS) (on Web of Knowledge) was searched from inception of the constituent databases to the most recent available versions, on 28 May 2015. The search was limited to the WoS Core Collection. The search strategy is given in [Appendix 4](#).

### Searching other resources

The review authors contacted authors of trials included in the systematic review and asked them if they knew of any other randomised controlled trials possibly relevant for this review. We also contacted experts in the field to identify additional trials.

Conference proceedings were handsearched and included: European Pressure Ulcer Advisory Panel (2000 to July 2015), European Wound Management Association (2001 to July 2015), and Wound, Ostomy and Continence Nurses Society (1994 to July 2015).

We screened the reference lists of all included trials and other relevant literature reviews to identify additional papers.

## Data collection and analysis

### Selection of studies

Two review authors (NVD and KVDB) independently screened titles and abstracts of all identified records. They retrieved and further checked for inclusion the full text of all potentially relevant records. NVD and KVDB sought the advice of a third review author (AVL) to resolve disagreements and documented reasons for exclusion of the records read in full.

### Data extraction and management

Two review authors (SW and JK) independently extracted data from the included trials. We developed a standardised form to use in this review. We pilot-tested the extraction form to identify whether we should collect additional data or improve the form.

The standardised form included the following data to be extracted: aim, design, setting, sample characteristics, description of intervention and comparison, outcome, and limitations. If necessary, we contacted the authors of the included studies to request additional information.

### Assessment of risk of bias in included studies

We evaluated the methodological quality of all included articles using The Cochrane Collaboration's 'Risk of bias' tool. This includes the following: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias (bias not covered elsewhere). We assigned each domain a judgement of 'low risk', 'high risk', or 'unclear risk' of bias, which we interpreted in accordance with Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Five review authors (MG, LS, JK, SW, DDM) independently assessed the risk of bias. If necessary, these authors sought the advice of DB to resolve disagreements.

We rated the quality of the evidence by using the software program GRADEpro. We assessed the relevance of the effect of the interventions based on a judgment of each participant-important outcome separately. GRADE allowed us to assess the quality of the body of evidence by taking into account five considerations: study limitations, consistency of effect, imprecision, indirectness, and publication bias (Guyatt 2011).

### Measures of treatment effect

We calculated risk ratios with a 95% confidence interval (CI) for binary outcomes and mean differences with a 95% CI for continuous data.

### Unit of analysis issues

The unit of analysis of randomised controlled trials and quasi-randomised trials were individual participants. If appropriate, we used following choices for other designs:

- Cross-over design: we planned to use the first treatment period.
- Cluster randomised controlled trials: we took into account the clustering effect.

### Dealing with missing data

The review authors contacted the authors of studies including missing data to request additional information. We used the intention-to-treat analysis (defined as analysed in the group to which the participants were randomised whether or not they received the intervention) and available case analysis (that is data as reported

by trialists without imputation for missing data) (Methodological Expectations of Cochrane Intervention Reviews). If data were missing to the extent that we could not include the trial in the analysis, we presented the results in a narrative way. If there was evidence of differential dropout, we gave consideration to imputation of the missing data.

### **Assessment of heterogeneity**

We planned to combine the studies in a meta-analysis if the clinical and methodological heterogeneity were acceptable. We judged the clinical heterogeneity based on population and intervention type. Due to large clinical and methodological heterogeneity, the data were not suitable for meta-analysis.

We planned to assess the statistical heterogeneity using the Chi<sup>2</sup> test at a significance level of 0.10 and calculate the I<sup>2</sup> statistic to quantify the heterogeneity. We would interpret the I<sup>2</sup> in accordance with Chapter 9 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and we would explore the source of heterogeneity using subgroup and sensitivity analysis. However, we did not perform a Chi<sup>2</sup> test nor calculated the I<sup>2</sup> statistic because a meta-analysis was not suitable.

### **Assessment of reporting biases**

A comprehensive search for eligible studies and alertness for duplication of data had to minimize the potential impact of publication and reporting bias. It was not possible to perform a funnel plot to assess reporting bias because of non-comparable designs and outcomes.

### **Data synthesis**

We entered data of all the trials in the software program Review Manager ([RevMan 2014](#)).

We planned to use a fixed-effects model when pooling the data, except for studies with a I<sup>2</sup> equal to or greater than 75%, in which case we would use a random-effects model. However, due to large clinical and methodological heterogeneity, it was not suitable to pool data. We presented the results in a narrative way.

~~We presented the outcomes as risk ratio for binary data using the Mantel-Haenszel statistical method. We reported continuous outcomes as mean differences with a 95% CI.~~

~~Because clinical and methodological heterogeneity were large, we presented the results in a narrative way.~~

We summarised the findings of the review using the software program GRADEpro. In a 'Summary of findings' table we presented participant-important outcomes.

## **Results**

### **Description of studies**

#### **Results of the search**

The literature search produced 4081 records, from which 36 full-text articles were further assessed for eligibility. Fourteen (quasi) randomised trials met the inclusion criteria for this review. One of these studies is awaiting classification, as Japanese translation is needed ([Wang 2011](#); [Characteristics of studies awaiting classification](#)). The PRISMA diagram in [Figure 1](#) presents the flow of the literature search.

#### **Included studies**

Thirteen (quasi) randomised trials were included in the qualitative synthesis (see [Characteristics of included studies](#)). The total number of participants included in the analyses was 1292.

#### **Design**

Eleven trials had a parallel group design. One trial had a cluster design ([Beeckman 2011](#)). One trial had a cross over design without a washout period between treatments ([Byers 1995](#)).

## Settings

Nine trials were performed at single centres. Of these, six were located in the United States, one in the Philippines, one in China and one in the Netherlands. Five of these single centre studies were conducted in hospitals and four in nursing homes.

One trial was conducted on geriatric wards of hospitals from one health service trust in the United Kingdom. Of the three remaining trials, one was conducted in 11 nursing homes in Belgium, one in 22 nursing homes in the Netherlands, and one in five long-term care centres in the United States.

## Participants

The mean age of the participants varied between 59 and 89 years across all studies. In more than half of the trials (7/13), the mean age was over 80 years. In the trial of Lewis-Byers ([Lewis-Byers 2002](#)), conducted in a nursing home, the participants were between 41 and 105 years old. Two other trials, of which one was conducted in a hospital and one in a nursing home, did not report data on participants' age ([Dieter 2006](#); [Lutz 1996](#)).

Most of the trials (n = 10) recruited participants with all types of incontinence. In one trial participants with fecal incontinence were included ([Wang 2011](#)). In another trial, only female participants with both urinary and fecal incontinence were included ([Byers 1995](#)). In a last trial, the type of incontinence was not reported ([Anthony 1987](#)).

In six trials, more than half of the participants showed neither redness nor skin erosion. Two trials included only participants without redness or skin erosion ([Brunner 2012](#); [Byers 1995](#)). Three trials included only participants with redness and/or skin erosion ([Baatenburg de Jong 2004](#); [Buckley 2014](#); [Wang 2011](#)). The two remaining trials did not report the proportion of participants with skin problems in the perineal environment ([Dieter 2006](#); [Schoonhoven 2015](#)).

## Interventions

Eight trials compared the application of a topical skin care product versus another topical skin care product for the prevention and/or treatment of incontinence-associated dermatitis (IAD) (first comparison, see [Types of interventions](#)). Because the main function of the products (moisturising versus skin protecting) was not always clear, we classified all topical skin care products broadly into skin cleansers and leave-on products. Leave-on products include moisturisers, skin protectants/barriers, and other functions, whether combined or not into one product.

- Two trials compared no-rinse skin cleansers with soap and water for the prevention (and treatment) of IAD ([Cooper 2001](#); [Byers 1995](#)).
- Eight trials compared various leave-on products (moisturisers, skin protectants/barriers, whether combined or not into one product):
  - A first trial compared Sudocrem® with a standard zinc oxide cream for the prevention and treatment of IAD ([Anthony 1987](#)).
  - A second trial compared a zinc oxide oil with a film forming skin product for the prevention and treatment of IAD ([Baatenburg de Jong 2004](#)).
  - A third trial compared a no-rinse skin cleanser and a leave-on product with a washcloth with cleansing, moisturising and skin protecting properties for the prevention and treatment of IAD ([Dieter 2006](#)).
  - A fourth trial compared a no-rinse skin cleanser and a skin cream with soap and water combined with a lotion for the prevention and treatment of IAD ([Lewis-Byers 2002](#)).
  - A fifth trial compared a no-rinse skin cleanser and moisturiser combined with a film forming skin product with a cleansing/moisturising/skin protecting washcloth for the prevention of IAD ([Brunner](#)

2012).

- A sixth trial compared Desitin® and Calmoseptine®, two commercial zinc oxide based products, for the treatment of IAD ([Buckley 2014](#)).
- A seventh trial compared a zinc oxide cream with a petrolatum ointment and a film forming skin product for the treatment of IAD ([Lutz 1996](#)).
- An eighth trial compared Dermlin® and Genetime® for the treatment of IAD ([Wang 2011](#)).

Two trials compared a structured skin care procedure with an unstructured skin care procedure (second comparison, see [Types of interventions](#)).

- One trial compared a washcloth with cleansing, moisturising and protecting properties with soap and water for the prevention and treatment of IAD ([Beeckman 2011](#)).
- One trial compared a washcloth impregnated with a lotion with soap and water for the prevention and treatment of any skin abnormalities en significant skin lesions ([Schoonhoven 2015](#)).

Two trials compared different frequencies of application of topical skin care products (fourth comparison, see [Types of interventions](#)):

- One trial compared two frequencies of a structured skin care procedure, including a skin cleanser and a leave-on product, for the prevention and treatment of IAD: every 6 versus 12 hours ([Conley 2014](#)).
- One trial compared three frequencies of the application of a film forming skin product in the treatment of IAD: every 24, 48 versus 72 hours for the treatment of IAD ([Lutz 1996](#)).

### Length of treatment

Most trials (n = 9) had a treatment period of 15 days or less. In three trials, nursing home residents were treated for three weeks ([Lewis-Byers 2002](#)), six weeks ([Schoonhoven 2015](#)) or three months ([Beeckman 2011](#)). In one trial the length of treatment was not reported ([Dieter 2006](#)).

### Sample size

Four trials had a sample size of 50 or less participants ([Baatenburg de Jong 2004](#); [Byers 1995](#); [Lewis-Byers 2002](#); [Lutz 1996](#)). In six trials, the sample size varied between 50 and 100 ([Anthony 1987](#); [Brunner 2012](#); [Conley 2014](#); [Cooper 2001](#); [Dieter 2006](#); [Wang 2011](#)). In three trials, more than 100 participants were included ([Beeckman 2011](#); [Buckley 2014](#); [Schoonhoven 2015](#)). The smallest sample size was 10 ([Byers 1995](#)), and the largest 450 ([Schoonhoven 2015](#)). Only the trial of [Beeckman 2011](#), with a sample size of 141 participants, mentioned that this sample size was sufficient for a statistical power of 0.85 ( $\alpha = 0.05$ ).

### Excluded studies

In total 22 trials were excluded from this review (see [Characteristics of excluded studies](#)), because of following reasons:

- Six trials were not (quasi) randomised controlled trials ([Bliss 2007](#); [Dealey 1995](#); [Holroyd 2014](#); [Kyung 2014](#); [Lyder 1992](#), [Zehrer 2004](#)).
- Twelve trials did not encompass any topical skin care product ([Al-Samarrai 2007](#); [Bates-Jensen 2003](#); [Bennett 1998](#); [Brown 1994](#); [Denat 2011](#); [Fader 2003](#); [Leiby 1994](#); [Netta-Turner 2008](#); [Pittman 2012](#); [Shin 2012](#); [Su 2015](#); [Sugama 2012](#)).
- One trial was not developed for the prevention or treatment of IAD ([Pinedo 2012](#)).
- One trial was restricted to the trial protocol ([Bauer 2007](#)).
- Two trials included participants younger than 18 years ([Iraji 2003](#), [James 1975](#)).

## Risk of bias in included studies

### *Allocation (selection bias)*

The risk of bias associated with random sequence generation was low in five trials ([Baatenburg de Jong 2004](#); [Beeckman 2011](#); [Buckley 2014](#); [Cooper 2001](#); [Schoonhoven 2015](#)), high in three trials ([Conley 2014](#); [Dieter 2006](#); [Lewis-Byers 2002](#)) and remained unclear in five trials ([Anthony 1987](#); [Brunner 2012](#); [Byers 1995](#); [Lutz 1996](#); [Wang 2011](#)). [Baatenburg de Jong 2004](#) used a computerized randomisation list provided by an independent biostatistics centre. [Schoonhoven 2015](#) used a computerized randomisation list set up by an independent statistician. [Beeckman 2011](#) and [Buckley 2014](#) performed a computerised randomisation at their own research centre. [Cooper 2001](#) used unmarked envelopes to randomise patients (first research site) or wards (other research sites). [Conley 2014](#) assigned participants enrolled on even numbered days to the intervention group and those enrolled on odd numbered days to the control group. [Dieter 2006](#) assigned participants based on the last digit of their medical record number. [Lewis-Byers 2002](#) assigned participants in odd numbered rooms to the trial protocol and participants in even-numbered rooms to the control group. The methods used by [Conley 2014](#), [Dieter 2006](#) and [Lewis-Byers 2002](#) were associated with a high risk of bias because allocation could be foreseen.

The risk of bias associated with allocation concealment was low in one trial ([Buckley 2014](#)), high in three trials ([Conley 2014](#); [Dieter 2006](#); [Lewis-Byers 2002](#)) and remained unclear in the remaining ten trials. In the study of [Buckley 2014](#), an independent surgical research unit, not linked to the trialists, performed the treatment allocation. [Conley 2014](#) used odd and even numbered days for treatment allocation. [Dieter 2006](#) used the last digit of medical record numbers for treatment allocation. [Lewis-Byers 2002](#) used odd and even numbered rooms for treatment allocation. The methods used by [Conley 2014](#), [Dieter 2006](#) and [Lewis-Byers 2002](#) were associated with a high risk of bias because allocation could be foreseen.

### *Blinding (performance bias and detection bias)*

The risk of performance bias remained unclear in one trial ([Anthony 1987](#)). [Anthony 1987](#) mentioned a double blind design but the researchers provided no further details. Blinding of participants and personnel was not possible in twelve trials due to visual differences in appearance and use of the skin care products.

The risk of detection bias was low in one trial ([Cooper 2001](#)), unclear in three trials ([Anthony 1987](#), [Dieter 2006](#), [Wang 2011](#)) and high in the remaining nine trials. [Cooper 2001](#) blinded the outcome assessment by asking two experts to assess the outcomes using photographs. [Anthony 1987](#) mentioned a double blind design but provided no further details. In the remaining trials no information on the assessment procedure was given, or the assessment was not blinded.

### *Incomplete outcome data (attrition bias)*

The risk of attrition bias due to incomplete outcome data was low in six trials ([Baatenburg de Jong 2004](#); [Buckley 2014](#); [Byers 1995](#); [Conley 2014](#); [Cooper 2001](#); [Lewis-Byers 2002](#)), high in two trials ([Anthony 1987](#); [Brunner 2012](#)) and unclear in the remaining five trials ([Beeckman 2011](#); [Dieter 2006](#); [Lutz 1996](#); [Schoonhoven 2015](#); [Wang 2011](#)).

### *Selective reporting (reporting bias)*

The risk of reporting bias due to selective reporting was low in eight trials ([Baatenburg de Jong 2004](#); [Beeckman 2011](#); [Buckley 2014](#); [Byers 1995](#); [Conley 2014](#); [Cooper 2001](#); [Lewis-Byers 2002](#); [Schoonhoven 2015](#)), high in four trials ([Anthony 1987](#); [Brunner 2012](#); [Dieter 2006](#); [Lutz 1996](#)) and unclear in one trial ([Wang 2011](#)). [Anthony 1987](#) did not report the results in sufficient detail (e.g. no parameters of erythema readings, only proportions of participants with change in red band). [Brunner 2012](#) did not report the statistical methods

clearly and provided only P values for some results. Furthermore, [Brunner 2012](#) did not give any reason for using a restricted sample size to study the time for skin breakdown. [Dieter 2006](#) and [Lutz 1996](#) did not report the statistical methods and provided no P values.

### **Other potential sources of bias**

One trial used a cross-over design without a wash-out period between interventions ([Byers 1995](#)). Consequently, bias could have been introduced from a carry-over effect.

At least five trials were sponsored by industry ([Baatenburg de Jong 2004](#); [Buckley 2014](#); [Byers 1995](#); [Cooper 2001](#); [Lutz 1996](#)). Concerning the trial of [Baatenburg de Jong 2004](#), the industrial company did the randomisation and data-analysis. Concerning the trial of [Lutz 1996](#), one of the authors was a member of the company delivering one of the trial products. In another trial ([Lewis-Byers 2002](#)) the corresponding author was a member of the company delivering the trial products. It was not clear how the involvement of industry may have influenced the results.

Detailed results of the risk of bias are presented in [Characteristics of included studies](#) and in [Figure 2](#) and [Figure 3](#).

### **Effects of interventions**

In the next paragraph, the data of included trials are described separately because of variation in tested skin care products or procedures and reported outcomes. The tables in [Characteristics of included studies](#) present a more detailed description of the trials. If possible, the data were entered in RevMan to calculate risk ratios and confidence intervals for use in this paragraph. The tables in [Data and analyses](#) present an overview of all relevant outcomes measured in the included studies and the numbers of studies measuring each outcome. Effect sizes (totals and subtotals) were not presented as no meta-analyses were performed.

#### **1. Any topical skin care product versus another topical skin care product**

For the same reason as described in [Included studies](#), the topical skin care products are divided into skin cleansers and leave-on products. Leave-on products consist of moisturisers, skin protectants/barriers, and other functions whether combined or not into one product.

#### **Skin cleansers**

##### **A skin cleanser versus soap and water**

Cooper et al ([Cooper 2001](#)) compared the use of the skin cleanser Clinisan® (Vernacare®) with the standard use of soap and water for the prevention and treatment of IAD. Clinisan® consists of a surfactant, emollients, dimethicone, an antibacterial agent and perfume, and has a pH 5.5.

This trial demonstrated that less participants treated with Clinisan® developed IAD during 14 days of follow-up. In the intervention group 6/33 (18.2%) of the elderly developed IAD and in the control group 15/32 (46.9%) of the elderly developed IAD. According to the analysis in RevMan, this effect was significant in favour of Clinisan® (risk ratio (RR) 0.39, 95% confidence interval (CI) 0.17 to 0.87, [Analysis 1.2](#)).

Byers et al ([Byers 1995](#)) compared the use of the skin cleanser Triple Care Cleanser® (Smith & Nephew®) with the standard use of soap and water for the prevention of IAD in a cross-over trial.

For an episode of urinary incontinence, the mean difference in cleansing time was 3.87 minutes in favour of the Triple Care Cleanser® (P < 0.001, 95% CI -4.31 to -3.43, Analysis 2.2). For an episode of both urinary and fecal incontinence, the mean difference in cleansing time was 9.68 minutes in favour of the Triple Care Cleanser® (P < 0.001, 95% CI -11.71 to -7.65, [Analysis 1.5](#)). The results of this cross-over trial were based on measurements over five treatment periods. The researchers did not provide results for the separate treatment periods. We did not find recent contact details to request more detailed information.

## Leave-on products (moisturisers, skin protectants/barriers, combined or not)

### **Sudocrem® versus standard zinc oxide cream**

Anthony et al ([Anthony 1987](#)) compared two different zinc oxide creams, Sudocrem® and a standard zinc oxide cream. Sudocrem® is claimed to have antiseptic properties and consists of 15.25% zinc oxide, 4.0% hydrous wool fat (hypo-allergenic), 1.01% benzyl benzoate, 0.15% benzyl cinnamate and 0.39% benzyl alcohol. The standard zinc oxide cream consists of 32.0% zinc oxide, 32.0% arachis oil, 0.045 calcium hydroxide, 0.5% oleic acid, 8% wool fat. Both creams were applied liberally to groin and buttocks with each diaper/pad change for 14 days.

During the trial 2/11 (18.2%) participants from the Sudocrem® group and 3/16 (18.8%) participants from the standard zinc oxide group developed IAD (RR 1.03, 95% CI 0.20 to 5.19, [Analysis 1.2](#)). A reduction in IAD severity was identified in 92.3% of the participants from the Sudocrem® group and 37.5% of the participants from the standard zinc oxide group after seven days. A reduction in IAD severity was identified in 84.6% of the participants from the Sudocrem® group and 50.0% of the participants from the standard zinc oxide group after 14 days. The researchers mentioned a significant greater improvement of IAD severity in favour of Sudocrem® at both time points ( $P < 0.01$ ). Because only percentages were provided, an analysis in RevMan was not possible for the outcome 'IAD severity'. We found no recent contact details of the authors to ask for more information.

### **Zinc oxide oil versus a film forming skin product**

Baatenburg de Jong et al ([Baatenburg de Jong 2004](#)) compared a zinc oxide oil with the film forming skin product Cavilon® No Sting Barrier Film (3M®) for the prevention and treatment of IAD. The zinc oxide oil was applied in accordance with nursing home protocol and removed every morning and evening before re-application and if necessary during diaper/pad changes. The film forming skin product was applied every 24, 48 or 72 hours depending on skin condition and frequency of diaper/pad change.

The researchers identified an improvement in IAD severity in both groups, with a significant greater improvement in the group treated with Cavilon® No Sting Barrier Film (3M®) ( $P = 0.04$ ). Because only a  $P$  value was reported, analysis in RevMan was not possible.

The cost of trial products and application related products was highest for zinc oxide oil (14.16 Euros, standard deviation (SD) 1.83) versus Cavilon® No Sting Barrier Film (3M®) (7.55 Euros, SD 8.60). Nursing time spent was also higher for zinc oxide oil (208.95 minutes, SD 53.84) versus Cavilon® No Sting Barrier Film (3M®) (161.96 minutes, SD 55.55). As a consequence, the total costs were higher for zinc oxide oil (102.96 Euros, SD 23.25) versus Cavilon® No Sting Barrier Film (3M®) (76.13 Euros, SD 25.48). The difference between groups was not measured statistically. The cost-effectiveness ratio was higher in participants treated with zinc oxide oil (98.06 Euros per 1 point improvement in skin condition) than in participants treated with Cavilon® No Sting Barrier Film (3M®) (28.36 Euros per 1 point improvement in skin condition). These economical data could not be analysed in RevMan, because the number of participants per group was not reported and the authors did not respond to our request for more details.

### **A no-rinse skin cleanser and a leave-on product versus a washcloth with cleansing, moisturising and skin protecting properties**

Dieter et al ([Dieter 2006](#)) compared the combined use of a no-rinse skin cleanser and a leave-on product with the use of a washcloth with cleansing, moisturising and skin protecting properties for the prevention and treatment of IAD. The researchers did not give the commercial name nor the ingredients of the products studied.

This study was described as an abstract. The outcomes reported were not suitable for this review. The authors did not respond to our request for more information.

### **A no-rinse skin cleanser and a skin cream versus soap and water and a lotion**

Lewis-Byers et al ([Lewis-Byers 2002](#)) compared the combined use of a no-rinse skin cleanser and a skin cream with the use of soap and water and a lotion for the prevention and treatment of IAD. The no-rinse skin

cleanser tested was Cavilon® Antiseptic Skin Cleanser (3M®). The skin cream was Cavilon® Durable Barrier Cream (3M®). The authors did not provide the commercial name nor the ingredients of the lotion. The participants of the first group were cleansed with the Cavilon® Antiseptic Skin Cleanser after each incontinent episode, and during the first incontinent episode per shift, a skin cream was applied. The participants of the second group were cleansed with soap (liquid or bar) and a disposable washcloth and water followed by the application of a lotion after each incontinence episode. Staff time per participant per day was measured for gathering supplies, setting supplies, cleansing participants and application of lotion or skin cream.

In this trial, 2/18 (11.1%) of the participants cared with Cavilon® Antiseptic Skin Cleanser and Cavilon® Durable Barrier Cream had IAD at the end of the trial period. Of the participants cared with soap and water and the lotion 4/13 (30.8%) had IAD at the end of the trial period. According to analysis in RevMan, this difference, in favour of Cavilon® Antiseptic Skin Cleanser combined with Cavilon® Durable Barrier Cream, was not significant (RR 0.36, 95% CI 0.08 to 1.68; [Analysis 1.1](#))

Additionally, this trial demonstrated that the severity of IAD did not significantly differ between the group cared with Cavilon® Antiseptic Skin Cleanser and Cavilon® Durable Barrier Cream (mean score: 0.28/4, SD 0.83) and the group cared with soap and water and the lotion (mean score 0.77/4, SD 1.30). The mean difference was -0.49 (95% CI -1.29 to 0.31, [Analysis 1.7](#)).

Staff time was shorter for the combined use of Cavilon® Antiseptic Skin Cleanser and Cavilon® Durable Barrier Cream than for the combined use of soap and water and the lotion. In the first group, staff time was 41 minutes per day for an average of seven incontinence episodes per day. The mean duration of cleansing was five minutes and for the application of Cavilon® Durable Barrier Cream two minutes. In the second group, staff time was 120 minutes per day for an average of 8 incontinence episodes per day. The mean duration of cleansing was 13 minutes and for the application of the lotion 2 minutes. Analysis in RevMan was not possible because standard deviations were not reported. The authors did not respond on our request for more details.

#### **A no-rinse skin cleanser and moisturiser and a film forming spray versus a washcloth with cleansing, moisturising and protecting properties**

Brunner et al. ([Brunner 2012](#)) compared the use of a cleansing and moisturising product followed by the application of a film forming skin product with the use of a washcloth (with cleansing, moisturising and protecting properties) for the prevention of IAD. The trial products were Cavilon® Skin Cleanser (3M®), Cavilon® No Sting Barrier Film (3M®) and Comfort Shield Perineal Care Washcloth Dimethicone 3%® (Sage Products Inc®).

The number of participants who developed IAD did not differ significantly between the two trial groups (RR 0.83, 95% CI 0.35 to 1.95, [Analysis 1.2](#)). In the group cared with Cavilon® Skin Cleanser (3M®) and Cavilon® No Sting Barrier Film (3M®), 7/31 participants (22.6%) developed IAD. In the group washed with the Comfort Shield Perineal Care Washcloth Dimethicone 3%®, 9/33 (27.3%) participants developed IAD.

The product costs per trial day were significantly higher for the combined use of Cavilon® Skin Cleanser (3M®) and Cavilon® No Sting Barrier Film (3M®) (6.59 US dollars) compared to the use of Comfort Shield Perineal Care Washcloth Dimethicone 3%® (2.67 US dollars) (P = 0.006). Because no standard deviations or other statistics were reported, analysis in RevMan was not possible.

#### **Comparison of two commercial zinc oxide products: Desitin® versus Calmoseptine®**

Buckley et al ([Buckley 2014](#)) compared Desitin® and Calmoseptine®, two zinc oxide based products, for the treatment of IAD. Desitin® is a paste consisting of 40% zinc oxide, lanolin, petrolatum and cod liver oil. Calmoseptine® is an ointment consisting of 20% zinc oxide, menthol, chlorothymol, glycerine, lanolin, sodium bicarbonate, phenol and thymol.

In each group, one of the zinc oxide products was applied twice daily and after each incontinence episode for six days. In addition, in both groups a structured skin care procedure for the treatment of IAD was applied. The skin care procedure was provided twice daily and as required by incontinence episodes. As part of the skin care procedure, nurses removed wet or soiled diapers/pads, cleansed the skin gently with a polyhexanide wound cleansing solution using gauze pads and soft tissue and applied a thin layer of zinc oxide product

prior to putting a new diaper/pad on.

According to this trial, the surface affected by IAD was significantly more reduced with the use of Calmoseptine® (P = 0.001, mean difference (MD) 81.60 cm<sup>2</sup>, 95% CI 36.87 to 127.33, [Analysis 1.3](#)). The number of participants with IAD completely healed on day six was significantly higher in favour of Calmoseptine® (Calmoseptine®: 14/56 (25.0%) versus Desitin®: 5/65 (7.7%), P = 0.009, RR 0.44, 95% CI 0.19 to 1.02, [Analysis 1.6](#)).

#### **Zinc oxide cream versus a petrolatum ointment**

Lutz et al ([Lutz 1996](#)) compared a zinc oxide cream (Baza®, Sween®) with a petrolatum ointment (Peri-Care®, Sween®) for the treatment of IAD. The zinc oxide group received zinc oxide cream three times per day and as necessary during 12 days. The petrolatum group received petrolatum ointment three times a day and as necessary.

The petrolatum ointment was less expensive than the zinc oxide cream in terms of daily cost of product use (petrolatum ointment 0.8 US dollars versus zinc oxide cream 1.2 US dollars) but no levels of significance were provided. Next to this, the researchers mentioned a significant improvement in IAD severity in both groups but provided no statistics. None of the groups showed a significant greater improvement in IAD severity than the other. Due to the limited reporting of statistical data, analysis in RevMan could not be performed. We found no recent contact details of the authors to ask for more information.

#### **Zinc oxide cream versus a film forming skin product**

Lutz et al ([Lutz 1996](#)) compared a zinc oxide cream (Baza®, Sween®) with a film forming skin product (Cavilon® No Sting Barrier Film, 3M®) for the treatment of IAD. The first group received Baza® three times per day and as necessary during 12 days. The second group received Cavilon® No Sting Barrier Film with a swab applicator every 24, 48 or 72 hours.

Baza® was less expensive than Cavilon® No Sting Barrier Film, in terms of daily cost of product use, if Cavilon® No Sting Barrier Film was applied every 24 or 48 hours (Baza® 1.2 US dollars versus Cavilon® No Sting Barrier Film 2.3 or 1.1 US dollars). Baza® was more expensive than Cavilon® No Sting Barrier Film, if the latter was applied every 72 hours (Baza® 1.2 US dollars versus Cavilon® No Sting Barrier Film 0.8 US dollars). No levels of significance were provided. In addition, the researchers mentioned a significant improvement in IAD severity in both groups but provided no statistics. None of the groups showed a significant greater improvement in IAD severity than the other. Due to the limited reporting of statistical data, analysis in RevMan could not be performed. We found no recent contact details of the authors to ask for more information.

#### **A petrolatum ointment versus a film forming skin product**

Lutz et al ([Lutz 1996](#)) compared a petrolatum ointment (Peri-Care®, Sween®) with a film forming skin product (Cavilon® No Sting Barrier Film, 3M®) for the treatment of IAD. The first group received Peri-Care® three times per day and as necessary during 12 days. The second group received Cavilon® No Sting Barrier Film, with a swab applicator every 24, 48 or 72 hours.

Peri-Care® was less expensive than Cavilon® No Sting Barrier Film, in terms of daily cost of product use, if the latter was applied every 24 or 48 hours (Peri-Care® 0.8 US dollars versus Cavilon® No Sting Barrier Film 2.3 or 1.1 US dollars). Peri-Care® costs the same as Cavilon® No Sting Barrier Film if the latter was applied every 72 hours (0.8 US dollars). The IAD severity improved significantly in both groups but no statistics were provided. None of the groups showed a significant greater improvement in IAD severity than the other. Due to the limited reporting of statistical data, analysis in RevMan could not be performed. We found no recent contact details of the authors to ask for more information.

#### **Dermlin® versus Genetime®**

Wang et al ([Wang 2011](#)) compared two commercial leave-on products, Dermlin® and Genetime®, for the treatment of IAD in the perianal environment. Dermlin® was described as an advanced wound healing product. Genetime® was described as a recombinant human epidermal growth factor.

This study was described as a short report in Chinese. The intervention nor the outcomes were clear from the English translation. We found no contact details of the author to ask for more information.

## **2. Any skin care procedure (method or frequency of application) versus any unstructured skin care procedure**

### **A washcloth with cleansing, moisturising and skin protecting properties versus soap and water**

Beeckman et al. ([Beeckman 2011](#)) compared a structured skin care procedure using a washcloth with cleansing, moisturising and skin protecting properties with the standard use of soap and water. The trial washcloth was the Comfort Shield Perineal Care Washcloth Dimethicone 3%® (Sage Products Inc®). The intervention group was washed daily with the Comfort Shield Perineal Care Washcloth® at routine perineal skin hygiene, and after each diaper/pad change. No towel rubbing was allowed. In case of an extremely soiled skin, a soft washcloth and lukewarm water were used to remove soiling and a soft towel to dry the skin. The control group was washed with a soft washcloth, soap (pH 6.5 to 7.5) and water at routine perineal skin hygiene, and after each diaper/pad change.

The authors concluded that, after 120 days, significantly less participants washed with the Comfort Shield Perineal Care Washcloth (intervention group) had IAD. After adjusting for clustering effect, 7.9% of participants washed with the washcloth had IAD versus 25.9% of the participants washed with soap and water (-washcloth 8.1% versus soap and water 27.1%,  $P < 0.001$ , RR 0.31, 95% CI 0.123 to 0.749, [Analysis 2.1](#)). Furthermore, IAD severity improved significantly in the intervention group (day 1: 6.9/10, day 120: 3.9/10,  $P < 0.001$ ) but not in the control group (day 1: 7.3/10, day 120: 6.4/10,  $P > 0.05$ ). At the end of the trial, IAD severity was significantly less in the intervention group (mean difference -2.50, 95% CI -3.195 to -1.851, [Analysis 2.2](#)). No participants had any bacterial or fungal infection during the trial.

### **A washcloth impregnated with a lotion versus soap and water**

Schoonhoven et al. ([Schoonhoven 2015](#)) compared the use of a washcloth impregnated with a lotion with soap and water for the prevention and treatment of skin abnormalities and skin lesions. The trial washcloths were the Wet Wash Gloves from Abena®.

The intervention group was washed daily bed with the Wet Wash Gloves which were heated in microwave before use. No towel rubbing was allowed. The control group was washed daily using tap water and soap (different types), wash gloves and towels.

The report of this trial provides results on skin abnormalities (e.g. erythema, erosions, discolorations of the wound bed) and significant skin lesions (non intact skin). These results, however, were not specific for IAD, but included any kind of skin abnormalities and lesions over the whole body.

## **3. Any method of application of a topical skin care product versus another method of application of the topical skin care product**

No suitable trials were found.

## **4. Any frequency of application of a topical skin care product versus another frequency of application of the topical skin care product**

### **Application of a skin cleanser and a leave-on product every 6 hours versus every 12 hours**

Conley et al ([Conley 2014](#)) tested a structured skin care procedure, including the application of a skin cleanser and a leave-on product, for the prevention and treatment of IAD. The skin cleanser and the leave-on product were applied every six hours or every 12 hours. The skin care procedure consisted of gentle cleansing the skin with the skin cleanser containing Aloe Vera mixed with water and a cleansing lotion followed by patting the skin dry. If no erythema was observed, a leave-on product with silicone was applied. If erythema was present, a leave-on product with zinc oxide and menthol was applied.

This trial identified no significant difference in the number of participants with IAD when performing the skin care procedure every six hours (56.4%) versus every 12 hours (60.0%) ( $P$  value = 0.718). No analysis in RevMan could be performed because the authors only provided percentages for the outcome of interest. The authors did not reply to our request for more details.

### Application of a film forming skin product every 24, 48 or 72 hours

Lutz et al ([Lutz 1996](#)) compared three frequencies of the application of a film forming skin product (Cavilon® No Sting Barrier Film (3M®): every 24, every 48 or every 72 hours.

The application of Cavilon® No Sting Barrier Film every 72 hours was the least expensive (0.8 US Dollar), followed by the application every 48 hours (1.1 US Dollar) and the application every 24 hours (2.3 US Dollar). Because no standard deviations were reported, analysis in RevMan was not possible.

The IAD severity improved significantly in the three groups but no statistics were mentioned. None of the groups showed a significant greater improvement in IAD severity than the other. Due to the limited reporting of statistical data, analysis in RevMan could not be performed. We found no recent contact details of the authors to ask for more information.

## Discussion

The aim of this review was to assess and compare the effectiveness of various products and procedures to prevent and treat incontinence-associated dermatitis (IAD) in adults. In this context the review focused on topical skin care products, structured skin care procedures, application methods for topical skin care products and frequencies of application of topical skin care products.

### Summary of main results

#### Primary outcomes

Three trials ([Brunner 2012](#); [Cooper 2001](#); [Lewis-Byers 2002](#)) assessed the effectiveness of topical skin care products (skin cleansers and leave-on products) concerning the outcome 'Number of participants with IAD (residual/new)'. Two of these trials tested a combined use of skin care products in each trial group (for example a skin cleanser and a leave-on product). One trial compared the use of a skin cleanser with soap and water ([Cooper 2001](#)). Another trial ([Beeckman 2011](#)) assessed whether a structured skin care procedure could reduce the same outcome as above in comparison with soap and water.

Based on the included trials, we found low quality evidence for the effectiveness of a skin cleanser (Clinisan® from Vernacare®) compared with soap and water. Besides, we found evidence of moderate quality for the effectiveness of a structured skin care procedure (using a washcloth with cleansing, moisturising and protecting properties; Comfort Shield Perineal Care Washcloth Dimethicone 3%®, Sage Products Inc®) compared with soap and water. No differences were found between topical skin care products (skin cleansers and leave-on products) in reducing the number of participants with IAD. However it should be noticed that the sample size of the latter trials was rather small (< 100 participants).

#### Secondary outcomes

One trial assessed the outcomes 'size of the skin lesion' (surface affected by IAD) and 'number of participants completely healed' ([Buckley 2014](#)). The researchers compared two different zinc oxide based leave-on products (Desitin® and Calmoseptine®) and identified a significant difference in favour of Calmoseptine® for both outcomes. However, the two products differed in the amount of zinc oxide being applied (20% in Calmoseptine®, 40% in Desitin®) and the presence of other active ingredients (such as menthol in Calmoseptine® and lanolin, petrolatum and cod liver oil in Desitin®). Consequently, it is not clear which amount of zinc oxide is optimal or which ingredients are pivotal for the treatment of IAD.

Low quality evidence was found for economics (outcomes 'cost of product', 'staff time', 'health economics'), based on a few small studies.

Two trials compared the costs of daily use of product for various leave-on products (zinc oxide based products, petrolatum ointment) with these of a film forming skin product (also a leave-on product) ([Baatenburg de Jong 2004](#); [Lutz 1996](#)). The methods used for economical analysis varied across these trials. It should also be

mentioned that the zinc oxide products and the petrolatum ointment were applied more frequently than the film forming skin product (at least twice daily versus every 24 or 48 or 72 hours). The findings from Lutz et al ([Lutz 1996](#)), which seem to be outdated, indicated that the film forming skin product Cavilon® No Sting Barrier Film (3M®) was more expensive if applied on a daily base. However, if this film forming skin product could be applied every 72 hours, then it would be less expensive than the zinc oxide cream Baza® (Sween®) and the petrolatum ointment Peri-Care® (Sween®) ([Lutz 1996](#)). Furthermore, if the costs for application-related products (gloves, spatula, gauze) were included, then the film forming skin product mentioned above, applied according to participants' needs, was less expensive than the zinc-oxide oil ([Baatenburg de Jong 2004](#)).

One trial demonstrated that the cost of daily use of product was significantly lower when using a washcloth with cleansing, moisturising and protecting properties (Comfort Shield Perineal Care Washcloth Dimethicone 3%®, Sage Products Inc®) versus the use of two separate leave-on products (Cavilon® Skin Cleanser, 3M® and Cavilon® No Sting Barrier Film, 3M®) ([Brunner 2012](#)).

Staff time was assessed in two small trials comparing soap and water and a skin cleanser ([Byers 1995](#); [Lewis-Byers 2002](#)). The findings from both trials indicated that staff time can be reduced when using a no-rinse skin cleanser (including Triple Care Cleanser® (Smith & Nephew®) and Cavilon® Antiseptic Skin Cleanser (3M®)). This could be expected as washing with a no-rinse skin cleanser does not need the filling and emptying of a water basin and the drying of the participant with a towel.

The cost-effectiveness ratio was calculated for two leave-on products (zinc oxide oil and a film forming skin protectant, [Baatenburg de Jong 2004](#)). When using the film forming skin protectant Cavilon® No Sting Barrier Film (3M®), the application frequency, application-related product costs and staff time were lower than when using zinc oxide oil. In addition, the IAD severity was also significantly lower. This trial concluded that the total costs (for products and staff time) per point improvement in IAD severity were in favour of the film forming skin protectant Cavilon® No Sting Barrier Film (3M®).

Three trials reported results on the outcome 'IAD severity' when comparing various leave-on products (zinc oxide products, petrolatum ointment, film forming skin protectant). In one small trial (n = 34), IAD severity improved more when using the film forming skin protectant Cavilon® No Sting Barrier Film (3M®) compared with zinc oxide oil ([Baatenburg de Jong 2004](#)). However, another similar trial, found no significant difference comparing the same film forming skin protectant with the zinc oxide cream Baza® (Sween®) ([Lutz 1996](#)). The latter trial included only 16 participants. A last trial found more improvement in terms of reduced skin redness when using Sudocrem® compared to a standard zinc oxide cream ([Anthony 1987](#)). Because of other differences in composition of these two products (such as amount of zinc oxide applied), it was not clear whether the ingredients responsible for the antiseptic properties of Sudocrem® determined the outcome. As described above, the trials of [Anthony 1987](#), [Baatenburg de Jong 2004](#) and [Lutz 1996](#) compared different leave-on products with each other. The overall findings of these trials suggested that IAD severity improved for all leave-on products.

One trial analysed the improvement in IAD severity when comparing a structured skin care procedure (washcloth with cleansing, moisturising and protecting properties) with soap and water ([Beeckman 2011](#)). In this trial, only residents washed with the washcloth (Comfort Shield Perineal Care Washcloth Dimethicone 3%®, Sage Products Inc®) showed a significant improvement in IAD severity.

## Overall completeness and applicability of evidence

This review included thirteen (quasi-) randomised controlled trials in a qualitative synthesis. The trials provided data for only two of the three proposed primary outcomes ('Number of participants with IAD residual (i.e. not healed)' and 'Number of participants with IAD new') and three of the seven proposed secondary outcomes ('Quantification of symptoms', 'Socio-economic measures' and 'Other outcomes'). We did not find data on four of seven participant-important outcomes: 'Number of participants not satisfied with treatment', 'Number of participants with pain due to IAD', 'Number of participants with pain due to skin care products or procedure'

and 'Adverse reaction due to skin care product or procedure'.

Although only thirteen trials were included, this review contains results on a wide range of topical skin care products (n = 15) and procedures (n = 3). The three subgroups of topical skin care products (see [Types of interventions](#)) were studied: no-rinse skin cleansers, moisturisers and skin protectants, either as separate products or combined into one product. Next to this, structured skin care procedures were studied. Nevertheless, the variation in products and procedures did not allow to pool data.

Almost half of the trials (n = 6) included participants with IAD as well as without IAD at start of the trial. Subgroup analysis were not performed. Consequently, we could not identify if the tested skin care products and procedures performed as well in the prevention and treatment of IAD.

## Quality of the evidence

A quantitative meta-analysis was not appropriate. The results from the different trials could not be pooled due to heterogeneity in participant population, skin care products, skin care procedure, outcomes and [measurement](#) tools ~~used to measure the outcomes~~.

Almost all trials showed at least two sources of bias. Selective reporting of trial results was a less common source of bias and was present in four trials ([Anthony 1987](#); [Brunner 2012](#); [Dieter 2006](#); [Lutz 1996](#)) and unclear in one trial ([Wang 2011](#)). Lack of blinding was the most common source of bias. Blinding of participants and personnel was not possible in all but one trial ([Anthony 1987](#)) due to visual differences in the skin care products. In only one trial ([Cooper 2001](#)), the outcome assessors were blinded by using photographs. Another possible source of bias was funding. At least five trials ([Baatenburg de Jong 2004](#); [Buckley 2014](#); [Byers 1995](#); [Cooper 2001](#); [Lutz 1996](#)) were funded by industry. The overall risk of bias in the included studies was high.

The GRADE assessment of quality of evidence could only be performed for two of the primary outcomes of this review, 'Number of participants with IAD new' and 'Number of participants with IAD residual (not healed)', including five single studies. This was due to a lack of statistical data (standard deviations, frequencies) necessary to calculate risk ratios or mean differences. The results from the GRADE assessment showed a low to very low quality for four trials, based on the risk of bias described above ([Anthony 1987](#); [Brunner 2012](#); [Cooper 2001](#); [Lewis-Byers 2002](#)). Furthermore, the imprecision of the point estimates was serious (large confidence interval) as a consequence of small sample sizes. Only the trial of Beeckman et al ([Beeckman 2011](#)) showed moderate quality. This was the only trial which proved (post hoc) an adequate sample size to detect real differences (statistical power).

As a conclusion, the quality of evidence for the prevention and management of IAD was poor. All data should be interpreted with caution.

## Potential biases in the review process

We performed a rigorous literature search to prevent missing relevant trials. We searched the Cochrane Incontinence Group Specialized Trial Register, major databases, reference lists and conference proceedings. In addition, we contacted specialists in the field and all authors of the included studies. Furthermore, all review authors are experts in the field, and performed multiple literature reviews on health care subjects and more specifically on the prevention and treatment of IAD in adults. Finally, we only identified three supplementary trials via reference lists. As a consequence, we believe the possibility of missing any relevant trial was low.

The review protocol was written out and followed in detail. All steps in the review process were performed by at least two (independently working) researchers. Next to this, the interpretation of the findings was done by all authors, working in different countries around the globe. This minimized the risk for errors, inaccuracies and influences of individual interest. Furthermore, experience was brought together.

The strict inclusion criteria limited the number of studies available for inclusion. Many trials were not performed in adults, not randomised, did not test topical skin care products or did not meet the proposed outcomes.

Whilst the inclusion criteria limited the list of included studies, the studies with the strongest set-up were used to draw conclusions.

## Agreements and disagreements with other studies or reviews

This review confirms the conclusions of two other systematic reviews. Beeckman et al. ([Beeckman 2009](#)) identified limited evidence for the effectiveness of various interventions for the prevention and treatment of IAD in adults. Furthermore, as in our review, soap and water performed poorly in the prevention and treatment of IAD. Next to this Corcoran and Woodward ([Corcoran 2013](#)), who focused their literature review on trials testing skin protectants, could not recommend any skin protectant over another due to a lack of evidence. Both reviews identified the same weaknesses in trial design: absence of power calculations in advance, small sample sizes, no blinded assessments and short trial periods. Based on the findings of our review and the reviews of Beeckman et al ([Beeckman 2011](#)) and Corcoran and Woodward ([Corcoran 2013](#)), it is clear that the available evidence on topical skin care products and procedures for prevention and management of IAD in adults is limited. More research to draw conclusions needs to be done.

The trials included in our review studied various topical skin care products (skin cleansers and leave-on products) for the prevention and treatment of IAD. Some commercial leave-on products seem to perform better than others, but we could not identify which ingredients were responsible for this difference in effectiveness. Recently Kottner and Beeckman published an overview of knowledge and recommendations concerning IAD and pressure ulcers in geriatric patients ([Kottner and Beeckman 2015](#)). These authors combined research findings with expert opinion. Kottner and Beeckman agreed with the existence of various skin care products concerning IAD and the lack of evidence on differences in benefits between products. In addition, they described that the performance of leave-on products not only depends on individual ingredients but especially on the combination of ingredients and the overall formulation. Furthermore, in accordance with our finding that most trials made no explicit distinction between the prevention and treatment of IAD, Kottner and Beeckman described the absence of a technology to promote skin barrier recovery after maceration in elderly.

## Authors' conclusions

### Implications for practice

There is little evidence on the effectiveness of interventions for preventing and treating IAD in adults. Consequently, we could not recommend any leave-on product (moisturiser, skin protectant, single or combined) above another. Using a leave-on product and avoiding soap is better than using nothing. The performance of leave-on products depends on the combination of ingredients, the overall formulation and the usage (e.g. amount applied).

### Implications for research

The current literature on interventions for preventing and treating IAD in adults consists of a few small trials of low to at most moderate quality. None of the trials identified were comparable in terms of trial set-up. Next to this, the functioning of the tested leave-on products was unclear (moisturising, skin protecting of both). Furthermore, we found no data on several (participants) important outcomes.

Future trials should try to overcome the methodological weaknesses identified through this review. First of all, we recommend the use of sample sizes large enough to reflect possible differences in effectiveness of interventions. A priori sample size calculation is mandatory. In addition, we recommend more efforts to blind the outcome assessment and to use valid methods for randomisation of participants and allocation concealment. Researchers must report the results of their trials accurately and according to the CONSolidated Standards of Reporting Trials ([CONSORT 2010](#)). We identified especially a lack in reporting standard deviations, absolute frequencies and levels of significance (P values). These data are essential to adequately interpret the research results and to compare outcomes across trials (e.g. in a meta-analysis). Another consideration is the time of follow up. For interventions aimed at preventing IAD, we recommend a follow-up

period of at least six weeks, based on the time to develop IAD which is 1 – 42 days ([Bliss 2011](#)). For interventions aimed at treating IAD, we recommend a follow-up period of at least three weeks, based on the time to IAD-healing which is 1 – 19 days ([Bliss 2011](#)). High quality confirmatory studies will enhance valuable conclusions about the effectiveness of products and procedures to prevent and treat IAD. We further recommend using standardized and comparable prevention and/or treatment regimens in different settings/regions.

While performing our review, we determined that the function of the skin care products (moisturising versus skin protecting) was not always clear. To enhance the interpretation and comprehensibility of the results of our review, we classified all products not being a skin cleanser as leave-on products. The latter group consisted of moisturisers and skin protectants, either as a separate product or combined into one product. To enhance correct product selection and comparability in practice and research, we highly recommend the use of a standardized language and terminology in the description of skin care products.

There is a need for uniform, relevant and participant-important outcomes. [Patients should be involved in the selection of these outcomes, to enhance the contribution of trial results in informed decision making.](#) Based on our experience with this review, we recommend the development of a core set of outcomes. This may improve the comparability across studies. More comparability is important to be able to pool results. Recently the IAD International Research Group has launched a project which aims to develop a core outcome set of well-defined IAD-related outcomes for clinical IAD research. This outcome set will also include validated tools for outcome measurement ([Beeckman 2015](#)).

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## Contributions of authors

Draft the protocol: all review authors

Develop the search strategy: Dimitri Beeckman and Aurélie Van Lancker with assistance from the Cochrane Incontinence Group Trials Search Co-ordinator

Develop the data extraction form: Dimitri Beeckman and Aurélie Van Lancker

Search for records: Nele Van Damme, Karen Van den Bussche, and Aurélie Van Lancker

Obtain copies of records: Sue Woodward and Jan Kottner

Selection of records: Nele Van Damme, Karen Van den Bussche, and Aurélie Van Lancker

Data extraction: Sue Woodward and Jan Kottner

Assessment of risk of bias: Mikel Gray, Lisette Schoonhoven, Jan Kottner, Sue Woodward, Dorien De Meyer and Dimitri Beeckman

Enter data in RevMan and GRADEpro: Nele Van Damme, Karen Van den Bussche, and Aurélie Van Lancker

Carry out the analysis: Dimitri Beeckman, Aurélie Van Lancker, and Dorien De Meyer

Interpret the analysis: all review authors

Draft the final review: all review authors

Update the review: all review authors

## Declarations of interest

Dimitri Beeckman: none known

Nele Van Damme: none known

Lisette Schoonhoven: none known

Aurélie Van Lancker: none known

Jan Kottner: none known

Hilde Beele: none known

Mikel Gray: none known

Sue Woodward: none known

Mandy Fader: none known

Karen Van den Bussche: none known

Ann Van Hecke: none known

Dorien De Meyer: [none known](#)

Sofie Verhaeghe: none known

## Differences between protocol and review

The original protocol stated that Embase would be searched as a separate database, as Cochrane now performs centralised searches of Embase and uploads the results into CENTRAL, the search of CENTRAL was considered adequate to retrieve relevant Embase records without the need to run a separate Embase search.

It was not possible to perform a funnel plot to assess reporting bias because of non-comparable designs and outcomes.

## Published notes

## Characteristics of studies

### Characteristics of included studies

#### *Anthony 1987*

<b>Methods</b>	Randomised controlled trial
<b>Participants</b>	67 patients from different geriatric wards requiring diapers/pads. Exclusion criteria: Patients with a current acute illness. Age (median): 81 years Gender (men/women): 10/54 Final analysis for development of IAD and reduction of erythema was on 57 patients Group A: 29 (4 died, had an intercurrent illness or were discharged) Group B: 28 (6 died, had an intercurrent illness or were discharged) Final analysis for bacteriological counts was on 43 patients

	Group A: 24 (5 incomplete bacteriological data) Group B: 19 (9 incomplete tintometric/bacteriological data)
<b>Interventions</b>	A: Sudocrem®, liberal application with each diaper/pad change B: Zinc oxide cream, liberal application with each diaper/pad change Length of treatment: 14 days Sudocrem® consists of: 15.25% zinc oxide, 4.0% hydrous wool fat (hypo-allergenic), 1.01% benzyl benzoate, 0.15% benzyl cinnamate and 0.39% benzyl alcohol. The zinc oxide cream consists of: 32.0% zinc oxide, 32.0% arachis oil, 0.045 calcium hydroxide, 0.5% oleic acid, 8% wool fat.
<b>Outcomes</b>	Number of participants with IAD (new) Group A: 3/16 Group B: 2/11 (No significant difference between groups) Reduction in erythema at day 7 Group A: 37.5% Group B: 92.3% (P < 0.01) Reduction of erythema at day 14 Group A: 50.0% Group B: 84.6% (P < 0.01) Corneocyte counts and parakeratotic cell ratios not reported Bacteriological counts reduction Greater reduction in bacteriological count in group A versus group B (P < 0.1)
<b>Notes</b>	

### Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Subjects were randomly allocated No further information is provided
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias)	Unclear risk	A double blind controlled trial No further information is provided
Blinding of outcome assessment (detection bias)	Unclear risk	A double blind controlled trial No further information is provided
Incomplete outcome data (attrition bias)	High risk	Not clear how patients were diagnosed with IAD, and who did that. Main outcome measure is redness, given in percentages. Not able to calculate number of patients with healing.
Selective reporting (reporting bias)	High risk	One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

### *Baatenburg de Jong 2004*

<b>Methods</b>	Randomised controlled trial
<b>Participants</b>	<p>34 nursing home patients</p> <p>Inclusion criteria: 18+ years; incontinent of urine, faeces or both; moderate to severe redness or moderate to severe erosion of the epidermis with mild to moderate involvement of the dermis caused by urine, faeces or both in the perianal/buttocks area</p> <p>Exclusion criteria: other significant skin disease or dermatological problem; medical condition according to the investigators opinion; participation in another trial in the previous 30 days</p> <p>Group A: 20 (mean age 85.1 years (SD 7.2); gender 60.0% female; mean BMI 24.9 (SD 6.1))</p> <p>Group B: 20 (mean age 83.3 years (SD 7.8); gender 73.7% female; mean BMI 22.9 (SD 3.4))</p> <p>Final analysis for skin condition assessment, reduction in redness, area of denudation was on 39 patients</p> <p>Final analysis for the cost analysis was on 30 patients (5 were healed, 4 died, 1 had high fever and hypotension)</p>
<b>Interventions</b>	<p>Group A: Zinc oxide oil according to nursing home protocol; removal of remaining zinc oxide every morning and evening before reapplication; reapplication if necessary during diaper/pad change; use of diapers</p> <p>Group B: Cavilon® No Sting Barrier Film (3M®) every 24, 48 to 72 hours depending on skin condition and frequency of diaper change; use of diapers/pads</p> <p>Length of treatment: 14 days</p>
<b>Outcomes</b>	<p>Skin condition assessment score</p> <p>Improvement in total skin damage score in favour of group A (p=0.04)</p> <p>Reduction in redness area</p> <p>Group A: 47.4% versus 15.0%</p> <p>Reduction in denudation area</p> <p>Group A: 42.9 versus 16.7%</p> <p>Reduction in denudation severity</p> <p>Group A: 35.7% versus 8.3%</p> <p>Product cost</p> <p>Group A: 14.16 Euros (SD 1.83) Group B: 7.55 Euros (SD 8.60)</p> <p>Nursing time</p> <p>Group A: 208.95 minutes (SD 53.84) Group B: 161.96 minutes (SD 55.55)</p> <p>Mean cost of nursing time</p> <p>Group A: 88.20 Euros (SD 22.88) Group B: 68.58 Euros (SD 23.61)</p> <p>Total cost (cost of treatment, cost of trial, cost of nursing)</p> <p>Group A: 102.96 Euros (SD 23.25) Group B: 76.13 Euros (SD 25.48)</p> <p>Cost-effectiveness ratio (ratio of difference in mean cost between groups and mean change in skin condition on a 12-point scale)</p> <p>Group A: 98.06 Euros/point improvement Group B: 28.36 Euros/point improvement</p>
<b>Notes</b>	Unclear in which group one patient dropped out

### Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomised by computer
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	Blinding impossible because of difference in product appearance and use.
Blinding of outcome assessment (detection bias)	High risk	No blinding, open label trial.
Incomplete outcome data (attrition bias)	Low risk	One patient not included in analysis. Reason not mentioned. 10 patients terminated the trial prematurely for the following non-trial related reasons: healing (5), death (4), high fever and hypotension (1)
Selective reporting (reporting bias)	Low risk	The trial protocol is available and all of the trial's pre-specified outcomes that are of interest in the review have been reported
Other bias	High risk	Trial sponsored by 3M, who makes Cavilon, who also did the randomisation and data analysis. No mention of this in the discussion, not clear how this may have influenced results. <b>Small sample size: 40 patients</b>

### Beeckman 2011

<b>Methods</b>	Clustered randomised controlled trial
<b>Participants</b>	<p>141 patients in 11 nursing home wards in 4 nursing homes at risk of/or affected by IAD</p> <p>Inclusion criteria: chronically incontinent for urine, stool, or double urinary and faecal incontinence and/or discolouration of the perineal skin, caused by urine or stool and not caused by pressure/shear and/or hyperhydrated skin.</p> <p>Exclusion criteria: admitted to hospital or admitted from another nursing home ward</p> <p>Group A: 73 (mean age 86.3 years; gender (male/female): 13/60; type of incontinence (urine/faeces/both): 45/21/7)</p> <p>Group B: 68 (mean age 85.9 years; gender (male/female): 15/53; type of incontinence (urine/faeces/both): 39/21/8)</p> <p>IAD prevalence and severity between groups not significantly different at baseline Group A: 22.3% Group B: 22.8% (P = 0.76)</p> <p>IAD severity between groups not significantly different at baseline Group A: 6.9/10 Group B: 7.3/10 (P = 0.99)</p>
<b>Interventions</b>	<p>Group A: Daily use of cellulose fiber/polyester premoistened washcloth (Comfort Shield Perineal Care Washcloth Dimethicone 3%®, Sage Products Inc®) for routine perineal skin hygiene and after each diaper/pad change; no towel rubbing; in case of extremely soiled skin soft washcloth and lukewarm water to remove soiling was allowed and a soft towel to dry the skin; use of diapers/pads with frequency of change according to protocol of the participant ward</p> <p>Group B: Daily use of soft washcloth, water and soap (pH 6.5 to 7.5) for routine perineal skin hygiene and after each diaper/pad change; no additional skin</p>

	protectant was applied; use of diapers/pads with frequency of change according to protocol of the participant ward Length of treatment: 120 days
<b>Outcomes</b>	Number of patients with IAD (residual) Group A: 8.1% Group B: 27.1% ( $t_{=}6.3$ , $P < 0.001$ ) IAD severity Group A: 3.8/10 Group B: 6.4/10 ( $t_{=}3.1$ , $P < 0.03$ ) Bacterial or fungal infection Group A: 0 Group B: 0
<b>Notes</b>	

### Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Simple randomisation was used to assign the wards to the experimental and control groups (SPSS)
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	No blinding of participants and personnel possible due to nature of intervention, i.e. washing with a washcloth with cleansing, moisturising and protecting properties or with soap and water.
Blinding of outcome assessment (detection bias)	High risk	No blinding of participants and personnel possible due to nature of intervention, i.e. washing with a washcloth with cleansing, moisturising and protecting properties or with soap and water.
Incomplete outcome data (attrition bias)	Unclear risk	No sufficient reporting of attrition/exclusions to permit judgement
Selective reporting (reporting bias)	Low risk	The trial protocol is available and all of the trial's pre-specified outcomes that are of interest in the review have been reported
Other bias	Low risk	

### Brunner 2012

<b>Methods</b>	Randomised controlled trial
<b>Participants</b>	64 hospitalised patients (critical and acute care) Inclusion criteria: age > 18 years; incontinence; intact skin Exclusion criteria: any erosion or sore on perineal skin; skin disease; known allergies influencing skin integrity Group A: 31 (mean age: 68.1 years; gender (male/female): 23/8) Group B: 33 (mean age: 66.4 years; gender (male/female): 20/13)
<b>Interventions</b>	Group A: No-rinse skin cleanser and moisturiser (Cavilon® Skin Cleanser, 3M®) and film forming skin product (Cavilon® No Sting Barrier Film, 3M®) Group B: Cleanser, moisturiser, barrier washcloth (Comfort Shield Perineal Care Washcloth Dimethicone 3%®; Sage Products Inc®)

	Length of treatment: not reported
<b>Outcomes</b>	<p>Number of participants with intact skin Group A: 24 Group B: 24</p> <p>Number of participants with mild skin breakdown Group A: 6 Group B: 5</p> <p>Number of participants with moderate skin breakdown Group A: 1 Group B: 4</p> <p>Number of participants with severe skin breakdown Group A: 0 Group B: 0</p> <p>Time to skin breakdown Group A: 213.3 hours Group B: 91.1 hours (<math>p = 0.045</math>)</p> <p>Cost per trial day Group A: \$6.59 Group B: \$2.67 (<math>p = 0.006</math>)</p>
<b>Notes</b>	Time to skin breakdown was based on $n = 6$ in both groups, unclear why the analysis was performed on 6 participants.

### Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported. Only mentioned randomly assigned.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	Not blinded
Blinding of outcome assessment (detection bias)	High risk	Not blinded
Incomplete outcome data (attrition bias)	High risk	Attrition not reported, and no account of how missing data were dealt with
Selective reporting (reporting bias)	High risk	P values not reported for Chi square test Statistical methods unclear (was an F-test conducted?), why were only $n = 6$ compared regarding average time for skin breakdown, duration of intervention not reported
Other bias	Unclear risk	<del>Sample size insufficient to meet desired significance level of 0.05.</del> Compliance with the study protocol not controlled

### Buckley 2014

<b>Methods</b>	Randomised controlled trial
<b>Participants</b>	<p>142 hospitalised patients</p> <p>Inclusion criteria: patients aged 12 years and older; urinary and/or faecal incontinence; IAD ; no known allergies to treatment ingredients</p> <p>Exclusion criteria: pre-existing pressure ulcer (grade 3 or 4) or other full thickness wound; other skin condition that may affect healing; inclusion would affect medical care; treatment with IAD agents in previous week.</p> <p>Group A: 73 (mean age: 59.1 years (SD 15.7); gender (male/female): 21/52; BMI:</p>

	<p>23.7 (SD 5.5); diabetes: 18; bed bound: 70; IAD score (median; range): 5 (3-8)  Group B: 69 (mean age: 58.8 years (SD 19.7); gender (male/female): 16/53; BMI: 22.8 (SD 5.1); diabetes: 15; bed bound: 68; IAD score (median; range): 6 (3-9)  Final analysis for change in IAD area affected was on 121 patients  Group A: 65 (discharged: 4; family withdrawal: 1; fungal infection or medical treatment: 3)  Group B: 56 (discharged: 7; no reason: 1; protocol deviation: 2; fungal infection or medical treatment: 3)</p>
<b>Interventions</b>	<p>Group A: 40% zinc oxide based paste (Desitin Max Strength Diaper Rash Paste®) applied twice daily and after incontinence episode; scrubbing and vigorous cleansing avoided; at diaper/pad change IAD cleaned with plain saline, a polyhexanide wound cleaner, gauze pads and soft tissue  Group B: 20% Zinc oxide based ointment (Calmoseptine® ointment) applied twice daily and after incontinence episode; scrubbing and vigorous cleansing avoided; at diaper/pad change IAD cleaned with plain saline, a polyhexanide wound cleaner, gauze pads and soft tissue  Length of treatment: 6 days</p>
<b>Outcomes</b>	<p>Number of participants completely healed (intention-to-treat analysis)  Group A: 7 Group B: 15 (P = 0.046)  Number of participants completely healed (per-protocol analysis)  Group A: 7 Group B: 14 (P = 0.039)  Mean change in IAD area affected  Group A: -40.7 (SD 174.6) Group B: -136.6 (SD 114.2) (P = 0.001)  Fungal infection: 4</p>
<b>Notes</b>	No mentioned to which group the patients with fungal infection were allocated to.

### Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Randomisation was computer-generated
Allocation concealment (selection bias)	Low risk	Treatment allocation was assigned by the surgical research unit, which was not linked to the trial team
Blinding of participants and personnel (performance bias)	High risk	Blinding for treatment not possible
Blinding of outcome assessment (detection bias)	High risk	Blinding for treatment not possible
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	Intention to treat analysis. All outcomes are reported
Other bias	Low risk	

**Byers 1995**

<b>Methods</b>	Cross-over trial
<b>Participants</b>	<p>10 white female residents from a US nursing home</p> <p>Inclusion criteria: intact perineal skin</p> <p>Exclusion criteria: Thigh-level amputations, not expected to live through the duration of the trial.</p> <p>Age (mean): 87 years</p> <p>gender (male/female): 0/10</p> <p>Brader score (mean): 9</p> <p>Duration of incontinence (mean): 8 months</p> <p>Final analysis for TEWL, erythema, pH and cleansing time was on 10 participants (1 transferred to other institution and 1 died)</p>
<b>Interventions</b>	<p>Group A (baseline/control): soap (Liquid Dial Soap®, The Dial Corp®) and water</p> <p>Group B (intervention): no-rinse skin cleanser (Triple Care Cleanser®, Smith &amp; Nephew®)</p> <p>Group C (intervention): no-rinse skin cleanser and skin protectant (Triple Care Cream®, Smith &amp; Nephew®)</p> <p>Group D (intervention): soap and water and skin protectant</p> <p>Group E (end/control): soap and water</p> <p>In all groups use of diapers/pads, cleansing three times per day.</p> <p>Length of trial: 15 weeks, 3 weeks per group (each skin care procedure was applied in each participant for three weeks, in random order)</p>
<b>Outcomes</b>	<p>TEWL (Trans-epidermal water loss)</p> <p>Group B: 12.1 Group C: 12.8 Group D: 11.6 Group E: 15.7.</p> <p>Group E vs. group B P = 0.02</p> <p>Group E vs. group D P = 0.01</p> <p>Group E vs. group C P = 0.03</p> <p>Erythema</p> <p>Group C: 156 Group E: 192 (P = 0.014)</p> <p>pH</p> <p>Group A: 6.88 Group B: 7.18 Group C: 7.21 Group D: 7.29 Group E: 7.50</p> <p>Group E vs. group B P = 0.006</p> <p>Group E vs. group C P = 0.04</p> <p>Group A vs. group D P = 0.002</p> <p>Group A vs. group C P &lt; 0.001</p> <p>Cleansing time</p> <p>Urine: No-rinse skin cleanser: 0.63 Soap and water: 4.50 (P &lt; 0.001)</p> <p>Stool and urine: No-rinse skin cleanser: 2.95 Soap and water: 12.6 (P &lt; 0.001)</p>
<b>Notes</b>	No evidence of skin break down (IAD developing) in any patient

**Risk of bias table**

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Two residents were randomly assigned to each order (6 orders). No more information is given

Allocation concealment (selection bias)	Unclear risk	Two residents were randomly assigned to each order (6 orders). No more information is given
Blinding of participants and personnel (performance bias)	High risk	No blinding
Blinding of outcome assessment (detection bias)	High risk	No blinding
Incomplete outcome data (attrition bias)	Low risk	12 residents were initially selected, data from 10 residents were available for analysis. 1 resident was transferred to a nursing home closer to her family; and 1 resident died of unrelated causes
Selective reporting (reporting bias)	Low risk	The trial protocol is available and all of the trial's pre-specified outcomes that are of interest in the review have been reported
Other bias	High risk	<del>Data from 10 patients</del> Cross-over design without washing-out periods 'Compliance with regimen was controlled'

### Conley 2014

<b>Methods</b>	Randomised controlled trial
<b>Participants</b>	<p>99 residents from Progressive Care Unit (PCU)</p> <p>Inclusion criteria: age &gt; 18 yrs; incontinence of urine and/or faeces; surgical patients who had an indwelling urinary catheter for &gt;2 days; patients who had a urinary catheter for any other length of time; patients with a rectal tube in situ for liquid stool.</p> <p>Exclusion criteria: Patients admitted from other units, outside facilities, or home</p> <p>Group A: 55 (mean age: 75 years; gender (male/female): 32/23; incontinence (urinary/bowel): 18/37; no dermatitis 20, mild/light red 22, moderate/red 5, severe/red 0; average number of length of stay: 9.13 days; average Braden score: 16)</p> <p>Group B: 44 (mean age: 67 years, gender (male/female): 19/25; incontinence (urinary/bowel): 17/27; no dermatitis 12, mild/light red 15, moderate/red 6, severe/red 2; average number of length of stay: 8.75 days; average Braden score: 14)</p> <p>Differences: patients group B were younger, but were more often affected by IAD and showed higher severity. Group A had more patients receiving enteral nutrition (21.8%) than controls (5.5%) (<math>P &lt; 0.001</math>); control group had more patients on pureed diet (23.6%) than intervention group (3.6%) (<math>P &lt; 0.001</math>); no significant difference reported for other measures at baseline (e.g. serum albumin, Braden score)</p>
<b>Interventions</b>	<p>Group A: skin care protocol performed every 6 hours and as needed</p> <p>Group B: skin care protocol performed every 12 hours and as needed</p> <p>Both groups: skin care protocol: gently skin cleansing with cleanser containing Aloe vera, water, cleansing lotion; after cleansing skin was patted dry; if no erythema application of a leave-on product including silicone; if erythema present application of a leave-on product with including zinc oxide and methanol</p> <p>Co-interventions: All nursing staff were given education on IAD and scoring erythema</p>

	Length of trial: 9 months
<b>Outcomes</b>	No dermatitis Group A: 43.6% Group B: 40% ( $p = 0.718$ ) Mild/light red Group A: 43.6% Group B: 25.5% ( $p < 0.001$ ) Moderate/red Group A: 7.1% Group B: 10.9% ( $p < 0.001$ ) Severe/red Group A: 1.9% Group B: 1.8% ( $p = 0.898$ )
<b>Notes</b>	Impossible to distinguish between prevention and treatment

### Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	To randomise the patients, those enrolled on even-numbered days were put in the intervention group. Those enrolled on odd-numbered days were put in the control group. Non random component in the sequence generation process.
Allocation concealment (selection bias)	High risk	Odd and even days used. Allocation can be foreseen
Blinding of participants and personnel (performance bias)	High risk	No blinding, also not possible due to nature of intervention: skin care every 12 or every 6 hours."
Blinding of outcome assessment (detection bias)	High risk	No blinding
Incomplete outcome data (attrition bias)	Low risk	No incomplete data reported. Table with outcomes reports same numbers at admission and discharge. 99 patients reported and 99 included. Patients were terminated from the trial upon transfer to another unit, discharge home, discharge to another facility or death. Insufficient reporting of attrition/exclusions to permit judgement
Selective reporting (reporting bias)	Low risk	The trial protocol is available and all of the trial's pre-specified outcomes that are of interest in the review have been reported
Other bias	Unclear risk	Insufficient information to assess whether an important risk of bias exists

### Cooper 2001

<b>Methods</b>	Randomised Controlled Trial
<b>Participants</b>	93 elderly patients from elderly care homes and hospitals Inclusion criteria: any patient suffering urinary incontinence, fecal incontinence, both, catheterised and bypassing urine. Exclusion criteria: none described Group A: 49 (median age: 79 years (IQR 73.5,86.5); gender (male/female): 22/27; nursing home residents/hospital patients: 28/21; median length of stay median: 0.38 years; healthy skin: 33; erythema: 9; broken skin: 5; average no.

	<p>incontinence episodes per 24 hours: 4; changes in mobility: 6)  Group B: 44 (median age: 85 years (IQR 79.8, 89.3) ; gender (male/female): 9/35; nursing home residents/hospital patients: 20/24; median length of stay median: 1.72 years; healthy skin: 33; erythema: 5; broken skin: 3; average no. incontinence episodes per 24 hours: 5; changes in mobility: 8)  Data complete for analysis on skin deterioration was on 87 patients. Gender difference between groups (statistical significance not reported)</p>
<b>Interventions</b>	<p>Group A: hospital soap (unperfumed and pH 9.5-10.5 (1% aqueous solution)) and water  Group B: Clinisan® (Vernacare®; skin cleanser with pH 5.5 – contains surfactant, emollients, dimethicone, antibacterial agent, perfume)  Both groups: Other skin protectants stopped  Co-interventions: All nursing staff were given education by researcher  Length of follow-up: 10 months (follow-up 14 days)</p>
<b>Outcomes</b>	<p>Number of patients healthy skin  Group A: 17/46 (37%) Group B: 27/41 (66%)  Number of patients deterioration of skin integrity  Group A: 14/46 (30%) Group B: 5/41 (12%)</p>
<b>Notes</b>	

### Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Patients were randomised by unmarked envelopes. No further information is given
Allocation concealment (selection bias)	Unclear risk	No clear description of concealment. No description of envelopes.
Blinding of participants and personnel (performance bias)	High risk	Not reported. Not possible due to differences in treatment
Blinding of outcome assessment (detection bias)	Low risk	Blinded assessment by two experts of outcomes using photographs.
Incomplete outcome data (attrition bias)	Low risk	Six patients not included in analysis. Reason not mentioned. 10 patients terminated the trial prematurely for the following non-trial related reasons: non-compliance (2), transfer to acute hospital (1), application of skin protectants in error and development of superficial blistering on the tights (1)
Selective reporting (reporting bias)	Low risk	The trial protocol is available and all of the trial's pre-specified outcomes that are of interest in the review have been reported
Other bias	Low risk	

**Dieter 2006**

<b>Methods</b>	Randomised controlled trial
<b>Participants</b>	94 patients from 3 adult medical/surgical hospital units Group A: 28 Group B: 35 group C: 31
<b>Interventions</b>	Group A: cleansing spray, washcloth, leave-on product Group B: disposable washcloth with cleansing, moisturising and skin protecting properties (dimethicone) Group C: disposable washcloth (discontinued at 4 weeks because of high rate of skin problems (29%) per incontinent episode).
<b>Outcomes</b>	Number of skin problems Group A: 14 Group B: 18 Number of patients with skin problems Group A: 6 Group B: 7 Average cost of treatment per patient Group A: 6.13 US Dollars Group B: 5.40 US Dollars
<b>Notes</b>	Data extraction was based on an abstract. The authors did not respond on our request for more details.

**Risk of bias table**

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Based on the last digit of medical record number
Allocation concealment (selection bias)	High risk	Based on the last digit of medical record number
Blinding of participants and personnel (performance bias)	High risk	Not possible due to visual differences between the interventions
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Attrition and exclusions not reported
Selective reporting (reporting bias)	High risk	Trial protocol not available, abstract P-values not reported
Other bias	Unclear risk	Study described in an abstract, without sufficient details

**Lewis-Byers 2002**

<b>Methods</b>	Randomised Controlled Trial
<b>Participants</b>	31 nursing home residents Inclusion criteria: incontinent for urine, stool or both Exclusion criteria: indwelling catheters Group A: 14 (range age: 63-105; gender (male/female): 1/13; type of incontinence (urine/faeces/both): 2/0/11; baseline skin condition rating normal skin: 9; redness, slight rash: 1; intense redness: 3; redness, small blisters: 0; skin erosion, loss of skin: 0)

	Group B: 18 (range age: 41/78; gender (male/female): 4/14; type of incontinence (urine/faeces/both): 1/4/13; baseline skin condition rating normal skin: 15; redness, slight rash: 1; intense redness: 0; redness, small blisters: 2; skin erosion, loss of skin: 0)
<b>Interventions</b>	Group A: cleansing with Cavilon® Antiseptic Skin Cleanser (3M®); during first incontinent episode per shift Cavilon® Durable Barrier Cream (3M®) was applied Group B: cleansing with soap (liquid or bar) and disposable washcloth and water followed by application of a lotion Both groups: cleansing after each incontinent episode Length of treatment: 3 weeks
<b>Outcomes</b>	Skin condition score Group A: 0.28 (SD 0.83) Group B: 0.77 (SD 1.30); not statistically significant (P value not reported) Pain score Group A: 0.11 (SD 0.47) Group B: 0.77 (SD 1.30); not statistically significant (P value not reported) Skin cleansing time including preparation Group A: 5 minutes per cleansing; 41 minutes per day Group B: 13 minutes per cleansing; 120 minutes per day
<b>Notes</b>	<b>Small sample size, in one institution only</b> Means and standard deviations of skin conditions and pain scores identical in group 1 (Table 3, page 49). Unclear whether this is correct or a typing error. Time was measured for an unknown subset of residents and modelled

### Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Patients were randomly assigned. Residents in even-numbered rooms were assigned to the control group, residents in odd numbered rooms were assigned to the trial protocol
Allocation concealment (selection bias)	High risk	Not present.
Blinding of participants and personnel (performance bias)	High risk	No blinding.
Blinding of outcome assessment (detection bias)	High risk	No blinding.
Incomplete outcome data (attrition bias)	Low risk	One patient not included in analysis. Reason not mentioned. One patient terminated the trial prematurely as result of regained continence.
Selective reporting (reporting bias)	Low risk	The trial protocol is available and all of the trial's pre-specified outcomes that are of interest in the review haven been reported

Other bias	Unclear risk	<del>Small sample size: 32 residents</del> <del>"Descriptive trial to compare the effect"</del> <a href="#">Corresponding author was a member of the company delivering the trial products</a>
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**Lutz 1996**

<b>Methods</b>	Randomised controlled Trial
<b>Participants</b>	40 subjects from health centre Inclusion criteria: history of incontinence, urine, faeces or both; moderate skin breakdown Exclusion criteria: not reported Group A: 8 Group B: 8 Group C: 8 Group D: 8 Group E: 8 All patients: 40 (age: not reported; Gender (male/female): not reported; Type of incontinence (urinary/fecal/both): 32/4/4; mean Braden score: 13.6 (SD 0.5); mean skin condition score: 6.0 (SD 0.3)) No statistically significant differences regarding Braden mean score between groups; no statistically significant differences regarding mean frequencies of incontinence episodes between groups.
<b>Interventions</b>	Group A: received petrolatum ointment (Peri-Care®, Sween®) three times per day and as necessary during 12 days Group B: received zinc oxide cream (Baza®, Sween®) three times per day and as necessary during 12 days Group C: received Cavilon® No Sting Barrier Film (3M®) every 24 hours during 12 days Group D: received No Sting Barrier Film every 48 hours during 12 days Group E: received No Sting Barrier Film every 72 hours during 12 days Length of treatment: six months
<b>Outcomes</b>	Skin condition score Skin condition scores decreased in all five groups (Figure 5, page 69) "There were no significant differences in skin condition among the five treatment groups at any time during the trial." (page 69) Amount of product use per day Group A: 13.6 g (SD 1.9) Group B: 16.1 g (SD 2.2) Group C: one applicator per patient per application Group D: one applicator per patient per application; Group E: one applicator per patient per application Cost per day Group A: 0.8 USD Group B: 1.2 USD Group C: 2.3 USD Group D: 1.1 USD Group E: 0.8 USD
<b>Notes</b>	Funding 3M Healthcare (Cavilon NSBF) Skin condition scores difficult to interpret

**Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random assignment. No further information provided.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	No blinding Blinding not possible due to difference in products.
Blinding of outcome assessment (detection bias)	High risk	No blinding
Incomplete outcome data (attrition bias)	Unclear risk	No incomplete data reported, insufficient reporting of attrition/exclusion.
Selective reporting (reporting bias)	High risk	One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis. Only average scores are mentioned. Trial protocol not published.
Other bias	Unclear risk	<del>Low sample size: 40 patients</del> Funded by 3M Healthcare

### Schoonhoven 2015

<b>Methods</b>	Clustered randomised controlled trial
<b>Participants</b>	500 nursing home residents; mean age 82.4 (SD 8.3); gender 71.0% female Inclusion criteria: elderly residents receiving bathing assistance Exclusion criteria: residents who showered or bathed in bath tub more than once a week; too sick to participate Group A: 290 (mean age 81.8 (SD 8.7); gender 70.7% female; BMI 25.4 kg/m <sup>2</sup> (SD 5.4)) Group B: 210 (mean age 83.3 (SD 7.5); gender 71.4% female; BMI 25.4 kg/m <sup>2</sup> (SD 6.0)) Final analysis was on 450 residents (Group A: 257 group B 193)
<b>Interventions</b>	Group A: Provision of bed bath with disposable wash cloths impregnated with lotion; heated in microwave before use; no towel drying Group B: Provision of daily bad bath using tap water, washbowls, soap (different types), wash gloves and towels Length of treatment: 6 weeks
<b>Outcomes</b>	Prevalence of any skin abnormalities Group A: 72.7% Group B: 77.6% Treatment x time interaction P = 0.04 Prevalence of significant skin lesions Group A: 36.0% Group B: 38.0% Treatment x time interaction P = 0.82 Prevalence of resistance Group A: 12.4% Group B: 9.4% Treatment x time interaction P = 0.71

<b>Notes</b>	Outcomes were not of interest for this review
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### Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by independent statistician
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	Blinding not possible due to visual differences between the interventions
Blinding of outcome assessment (detection bias)	High risk	No blinding. Analysis by blinded statistician.
Incomplete outcome data (attrition bias)	Unclear risk	Unclear consideration of losses of follow-up. denominator of prevalence of skin lesions n = 500 (table 3, page 116), but n = 50 were lost during the study
Selective reporting (reporting bias)	Low risk	No selective reporting apparent
Other bias	Low risk	

### Wang 2011

<b>Methods</b>	Randomised controlled trial
<b>Participants</b>	62 in hospital patients with fecal incontinence lasted for 6 to 21 days Inclusion criteria: long term immobilization; aged more than 80 years old; fecal incontinence with perianal skin damage. Group A: 31 Group B: 31 No differences between patients in the intervention and the control group at baseline for age, gender and severity of patient's condition
<b>Interventions</b>	Group A: cleansing of the perianal region after bowel spray with Dermlin (advanced wound healing product) Group B: cleansing of the the perianal region after bowel spray with Genetime (recombinant human epidermal growth factor) Length of treatment: observation of the results after five days of treatment
<b>Outcomes</b>	Proportion of patients with IAD healed (predefined outcome) Not clearly described, translation from Chinese
<b>Notes</b>	

### Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear from Chinese translation

Allocation concealment (selection bias)	Unclear risk	Unclear from Chinese translation
Blinding of participants and personnel (performance bias)	High risk	Not possible due to visual differences between the skin care products
Blinding of outcome assessment (detection bias)	Unclear risk	Unclear from Chinese translation
Incomplete outcome data (attrition bias)	Unclear risk	Unclear from Chinese translation
Selective reporting (reporting bias)	Unclear risk	Unclear from the Chinese translation
Other bias	Unclear risk	Unclear from the Chinese translation, rather short report (two pages in the journal)

*Footnotes***Characteristics of excluded studies*****Al-Samarrai 2007***

<b>Reason for exclusion</b>	No topical skin care product studied: method for improving protocol compliance
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***Bates-Jensen 2003***

<b>Reason for exclusion</b>	No topical skin care products studied: an exercise and incontinence intervention
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***Bauer 2007***

<b>Reason for exclusion</b>	Report of a study protocol
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***Bennett 1998***

<b>Reason for exclusion</b>	No topical skin care products studied: low airloss hydrotherapy
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***Bliss 2007***

<b>Reason for exclusion</b>	No randomised controlled trial
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***Brown 1994***

<b>Reason for exclusion</b>	No topical skin care products studied: diapers and pads
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***Dealey 1995***

<b>Reason for exclusion</b>	No randomised controlled trial: a preliminary trial
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***Denat 2011***

<b>Reason for exclusion</b>	No topical skin care products studied: perianal pouch and adult containment brief
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**Fader 2003**

<b>Reason for exclusion</b>	No topical skin care products studied: absorbent pads
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**Holroyd 2014**

<b>Reason for exclusion</b>	No randomised controlled trial: product evaluation by hospitals
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**Iraji 2003**

<b>Reason for exclusion</b>	Pediatric population
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**James 1975**

<b>Reason for exclusion</b>	Pediatric population
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**Kyung 2014**

<b>Reason for exclusion</b>	No randomised controlled trial: no random allocation of participants
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**Leiby 1994**

<b>Reason for exclusion</b>	No topical skin care products studied: reusable underpads
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**Lyder 1992**

<b>Reason for exclusion</b>	No randomised controlled trial: no random allocation of participants
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**Netta-Turner 2008**

<b>Reason for exclusion</b>	No topical skin care products studied: rectal trumpet
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**Pinedo 2012**

<b>Reason for exclusion</b>	No intervention for preventing or treating incontinence-associated dermatitis: intervention to decrease the rate of faecal incontinence
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**Pittman 2012**

<b>Reason for exclusion</b>	No topical skin care products studied: bowel management system catheter, rectal/nasopharyngeal trumpet,
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**Shin 2012**

<b>Reason for exclusion</b>	No topical skin care products studied: uncoated paper
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**Su 2015**

<b>Reason for exclusion</b>	No topical skin care products studied: suspension positioning system
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**Sugama 2012**

<b>Reason for exclusion</b>	No topical skin care products studied: improved absorbent pad
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**Zehrer 2004**

<b>Reason for exclusion</b>	No randomised controlled trial: descriptive trial
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Footnotes

**Characteristics of studies awaiting classification****Kajii 2005**

<b>Methods</b>	Clustered randomised controlled trial
<b>Participants</b>	101 elderly from 5 hospitals and health care facilities for elderly, who used a diaper for their incontinence Age (average): 84.9
<b>Interventions</b>	Group A: skin protection cleaning foam 2 times per day Group B: skin protection cleaning foam 4 times per day Group C: conventional care using warm water Length of treatment: 6 days
<b>Outcomes</b>	The amount of moisture Group A: 53.6 (SD 10.0) Group B: 70.5 (SD 9.1) Group C: 49.7 (SD 7.2) The amount of sebum Group A: 2.1 (SD 3.1) Group B: 5.0 (SD 5.4) Group C: 1.5 (SD 1.5)
<b>Notes</b>	A translation is awaited The outcomes reported were not of interest for this review

Footnotes

**Characteristics of ongoing studies**

Footnotes

**Summary of findings tables**

**1 Any topical skin care product versus another topical skin care product**

Any topical skin care product versus another topical skin care product <b>undefined</b>						
<b>Patient or population:</b> <u>adults with incontinence</u> <del>preventing and treating incontinence-associated dermatitis in adults</del>						
<b>Setting:</b> <u>hospitals and nursing homes</u>						
<b>Intervention:</b> <u>A</u> any topical skin care product						
<b>Comparison:</b> another topical skin care product						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with <u>another topical skin care product B</u>	Risk with <u>Any topical skin care product A</u>				
<b>Number of participants with IAD (residual, i.e. not healed)–</b> <u>(1)</u> A no-rinse skin cleanser and a skin cream (A) versus soap and water and a lotion (B)	Study population		RR 0.36	31 (1 RCT)	⊕⊕⊕⊕ VERY LOW	Based on one small study
	308 per 1.000	111 per 1.000 (25 to 517)	(0.08 to 1.68)			
<b>Number of participants with IAD (new)–</b> <u>(1)</u> A skin cleanser (A) versus soap and water (B)	Study population		RR 0.39	65 (1 RCT)	⊕⊕⊕⊕ LOW	Based on one small study and sponsored by industry
	469 per 1.000	183 per 1.000 (80 to 408)	(0.17 to 0.87)			
<b>Number of participants with IAD (new)–</b> <u>(2)</u> Sudocrem (A) versus zinc oxide cream (B)	Study population		RR 1.03	27 (1 RCT)	⊕⊕⊕⊕ LOW	Based on one small study
	182 per 1.000	187 per 1.000 (36 to 944)	(0.20 to 5.19)			
<b>Number of participants with IAD (new)–</b> <u>(3)</u> A no-rinse skin cleanser/moisturiser and a film forming skin product (A) versus a cleansing/moisturising/skin protecting washcloth (B)	Study population		RR 0.83	64 (1 RCT)	⊕⊕⊕⊕ LOW	Based on one small study. Corresponding author was member of the company who delivered the study products.
	273 per 1.000	226 per 1.000 (95 to 532)	(0.35 to 1.95)			

\***The risk in the intervention group** (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; **RR:** Risk ratio; **OR:** Odds ratio;

#### 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

#### Footnotes

## 2 Any skin care procedure (method or frequency of application) versus any unstructured skin care procedure

Any skin care procedure (method or frequency of application) versus any unstructured skin care procedure **undefined**

**Patient or population:** ~~preventing and treating incontinence-associated dermatitis in adults~~ adults with incontinence

**Setting:** nursing homes

**Intervention:** aAny skin care procedure (method or frequency of application)

**Comparison:** any unstructured skin care procedure

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with any unstructured skin care procedure (B)	Risk with Any skin care procedure (method or frequency of application) (A)				
<b>Number of participants with IAD (residual, i.e. not healed) — (1) A washcloth with cleansing, moisturising and protecting properties (A) versus water and pH neutral soap (B)</b>	Study population		RR 0.31 (0.12 to 0.79)	121 (1 RCT)	⊕⊕⊕⊕ MODERATE	Based on one study
	259 per 1.000	80 per 1.000 (31 to 204)				

\***The risk in the intervention group** (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; **RR:** Risk ratio; **OR:** Odds ratio;

#### 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

### Footnotes

## Additional tables

## References to studies

### Included studies

#### **Anthony 1987**

Anthony D, Barnes E, Malone-Lee J, Pluck R. A clinical study of Sudocrem in the management of dermatitis due to the physical stress of incontinence in a geriatric population. *Journal of Advanced Nursing* 1987;12(5):599-603. [Other: sr-incont519]

#### **Baatenburg de Jong 2004**

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#### **Beeckman 2011**

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**Other published versions of this review****Data and analyses****1 Any topical skin care product versus another topical skin care product**

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Number of participants with IAD (residual, i.e. not healed)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
1.1.1 A no-rinse skin cleanser and a skin cream (A) versus soap and water and a lotion (B)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
1.2 Number of participants with IAD (new)	3		Risk Ratio (M-H, Fixed, 95% CI)	No totals
1.2.1 A skin cleanser (A) versus soap and water (B)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
1.2.2 Sudocrem (A) versus zinc oxide cream (B)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
1.2.3 A no-rinse skin cleanser/moisturiser and a film forming skin product (A) versus a cleansing/moisturising/skin protecting washcloth (B)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals

1.3 Surface affected by IAD (measurement of size of lesion)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.3.1 Desitin (A) versus Calmoseptine (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.4 Cost of products	2		Mean Difference (IV, Fixed, 95% CI)	No totals
1.4.1 A zinc oxide cream (A) versus a petrolatum ointment (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.4.2 A zinc oxide cream (A) versus a film forming skin product (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.4.3 A petrolatum ointment (A) versus a film forming skin product (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.4.4 A no-rinse skin cleanser/moisturiser and a film forming skin product (A) versus a cleansing/moisturising/skin protecting washcloth (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.5 Staff time	2		Mean Difference (IV, Fixed, 95% CI)	No totals
1.5.1 A skin cleanser/moisturiser (A) versus soap and water (B) (urine)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.5.2 A skin cleanser/moisturiser (A) versus soap and water (B) (urine and stool)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.5.3 A no-rinse skin cleanser and a skin cream (A) versus soap and water and a lotion (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.6 Number of participants with IAD completely healed	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
1.6.1 Desitin (A) versus Calmoseptine (B)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
1.7 IAD severity	3		Mean Difference (IV, Fixed, 95% CI)	No totals
1.7.1 Sudocrem (A) versus zinc oxide cream (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.7.2 A no-rinse skin cleanser and skin cream (A) versus soap and water and a lotion (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals

1.7.3 A zinc oxide cream (A) versus a petrolatum ointment (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.7.4 A zinc oxide cream (A) versus a film forming skin product (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
1.7.5 A petrolatum ointment (A) versus a film forming skin product (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals

## 2 Any skin care procedure (method or frequency of application) versus any unstructured skin care procedure

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Number of participants with IAD (residual, i.e. not healed)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
2.1.1 A washcloth with cleansing, moisturising and protecting properties (A) versus water and pH neutral soap (B)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
2.2 IAD Severity	1		Mean Difference (IV, Fixed, 95% CI)	No totals
2.2.1 A washcloth with cleansing, moisturising and protecting properties (A) versus water and pH neutral soap (B)	1		Mean Difference (IV, Fixed, 95% CI)	No totals
2.3 Bacterial and fungal infection	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals
2.3.1 A washcloth with cleansing, moisturising and protecting properties (A) versus water and pH neutral soap (B)	1		Risk Ratio (M-H, Fixed, 95% CI)	No totals

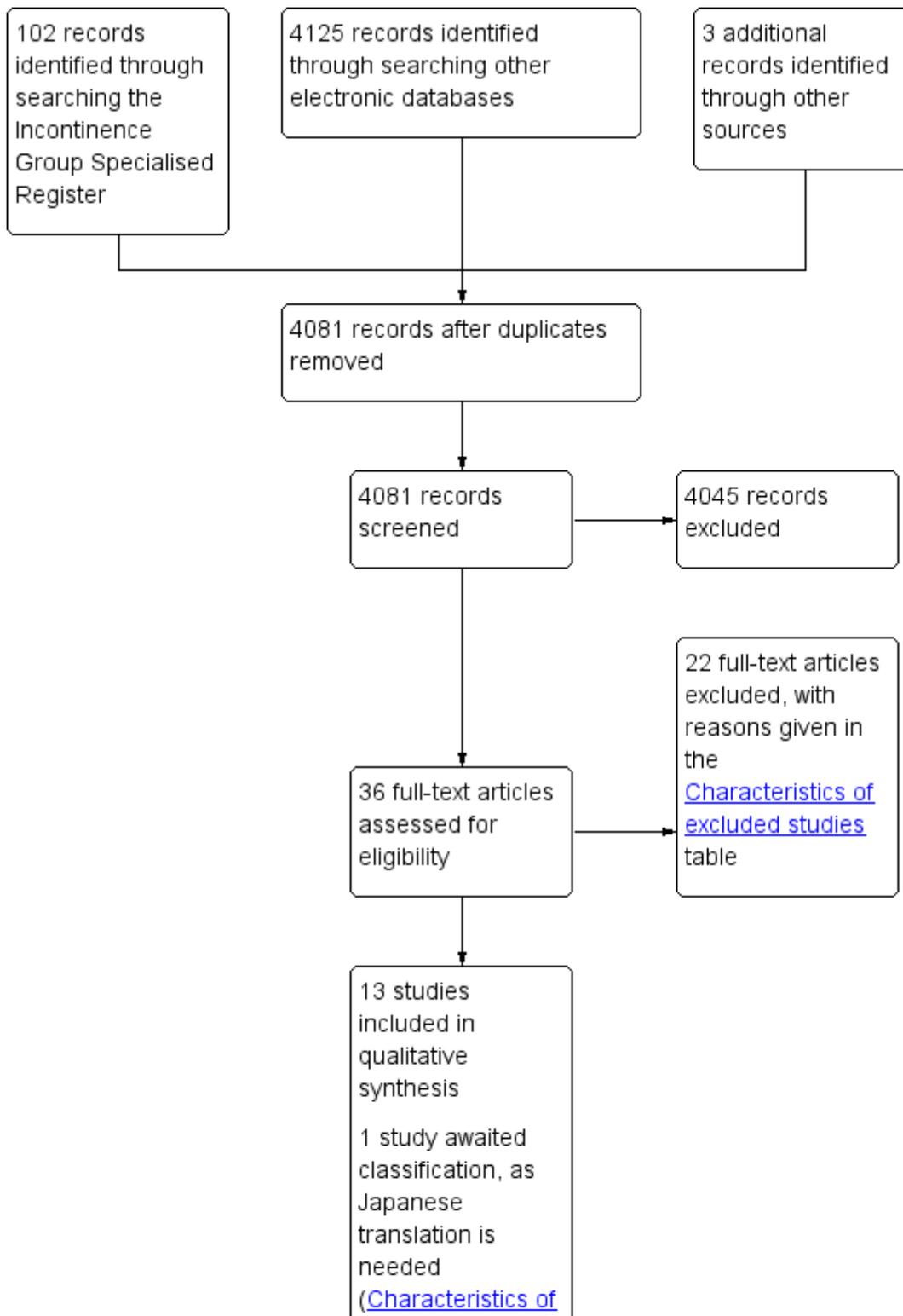
## 3 Any frequency of application of a topical skin care product versus another frequency of application of the topical skin care product

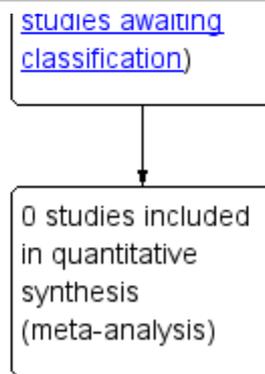
Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
3.1 Cost of products	1		Mean Difference (IV, Fixed, 95% CI)	No totals
3.1.1 Application of a film forming skin product every 24, 48 or 72 hours	1		Mean Difference (IV, Fixed, 95% CI)	No totals

3.2 IAD Severity	1		Mean Difference (IV, Fixed, 95% CI)	No totals
3.2.1 Application of a film forming skin product every 24, 48 or 72 hours	1		Mean Difference (IV, Fixed, 95% CI)	No totals

## Figures

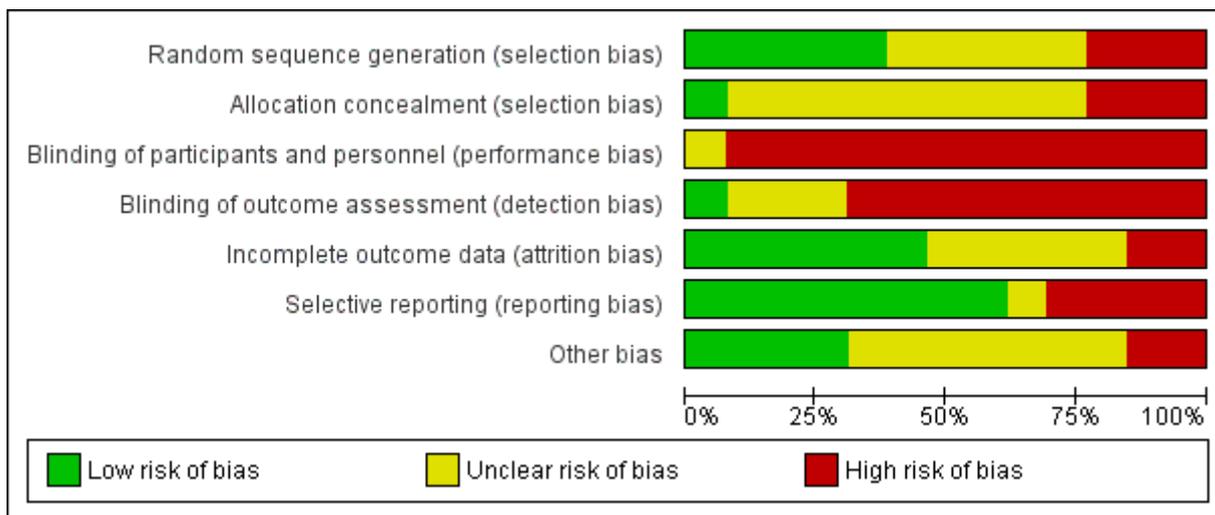
**Figure 1**





PRISMA study flow diagram.

**Figure 2**



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

**Figure 3**

	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
Anthony 1987	?	?	?	?	-	-	?
Baatenburg de Jong 2004	+	?	-	-	+	+	-
Beeckman 2011	+	?	-	-	?	+	+
Brunner 2012	?	?	-	-	-	-	?
Buckley 2014	+	+	-	-	+	+	+
Byers 1995	?	?	-	-	+	+	-
Conley 2014	-	-	-	-	+	+	?
Cooper 2001	+	?	-	+	+	+	+
Dieter 2006	-	-	-	?	?	-	?
Lewis-Byers 2002	-	-	-	-	+	+	?
Lutz 1996	?	?	-	-	?	-	?
Schoonhoven 2015	+	?	-	-	?	+	+
Wang 2011	?	?	-	?	?	?	?

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

## Sources of support

### Internal sources

- No sources of support provided

### External sources

- The National Institute for Health Research (NIHR), UK  
The NIHR is the largest single funder of the Cochrane Incontinence Group.

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of

## Feedback

## Appendices

### 1 Cochrane Incontinence Group Specialised Register search strategy

We used the following terms to search the Cochrane Incontinence Group Specialised Register:

((({DESIGN.CCT\*} OR {DESIGN.RCT\*}) AND ({TOPIC.URINE.INCON.Skin\*} OR {TOPIC.FAECAL.INCON.Skin\*}))

All searches were of the keyword field of [Reference Manager 2012](#). The date of the last search was 29 April 2015.

### 2 CENTRAL, MEDLINE and MEDLINE In-Process search strategy

**Cochrane Central Register of Controlled Trials** April 2015, **Ovid MEDLINE(R)** 1946 to May Week 3 2015, **Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations** 26 May 2015 on OvidSP were searched on 27 May 2015 using the following search:

1. controlled clinical trial.pt.
2. randomized controlled trial.pt.
3. randomized controlled trials/
4. random allocation/
5. double blind method/
6. single blind method/
7. clinical trial.pt.
8. exp clinical trial/
9. placebos/
10. placebo\$.tw.
11. random\$.tw.
12. research design/
13. volunteer\$.tw.
14. (clin\$ adj25 trial\$).tw.
15. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).tw.
16. factorial.tw.
17. cross-over studies/
18. crossover.tw.
19. latin square.tw.
20. (balance\$ adj2 block\$).tw.

21. trial.ti.
22. (animals not humans).sh.
23. or/1-21
24. 23 not 22
25. (incontinen\* adj25 dermatitis).tw.
26. (incontinen\* adj25 skin).tw.
27. exp dermatological agents/ and Pressure Ulcer/
28. (incontinen\* adj2 lesion\*).tw.
29. (moisture adj2 lesion\*).tw.
30. (macerat\* adj2 skin\*).tw.
31. (perine\* adj2 dermatitis).tw.
32. Diaper Rash/
33. 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
34. 33 and 24
35. dermatitis/ or dermatitis, contact/ or dermatitis, irritant/ or diaper rash/ or erythema/
36. Pressure Ulcer/
37. skin integrity.tw.
38. skin inflam\*.tw.
39. (skin adj2 loss\*).tw.
40. (skin adj2 red\*).tw.
41. (skin adj2 blister\*).tw.
42. (skin adj2 bull\*).tw.
43. (skin adj2 perine\*).tw.
44. erythema\*.tw.
45. (skin adj2 (erod\* or erosion\*)).tw.
46. (skin adj2 barrier\*).tw.
47. secondary skin infect\*.tw.
48. (cutaneous adj2 loss\*).tw.
49. (cutaneous adj2 (red\* or blister\* or bull\* or perine\* or barrier\* or loss\* or inflam\* or integrity)).tw.
50. (epiderm\* adj2 loss\*).tw.
51. (epiderm\* adj2 (red\* or blister\* or bull\* or perine\* or barrier\* or loss\* or inflam\* or integrity)).tw.
52. (skin adj2 rash\*).tw.
53. (rash\* adj2 (epiderm\* or cutaneous or cuticle)).tw.

54. (dermatit\* adj2 (contact or irrit\*)).tw.
55. (skin adj2 damag\*).tw.
56. (skin adj2 lesion\*).tw.
57. Perineum/
58. perirect\*.tw.
59. perianal.tw.
60. buttocks/ or thigh/
61. intergluteal.tw.
62. perigenital.tw.
63. perine\*.tw.
64. inguinal.tw.
65. Intertrigo/
66. (buttock\* or thigh\*).tw.
67. genital\*.tw.
68. intertrig\*.tw.
69. genitalia/ or genitalia, female/ or vulva/ or genitalia, male/ or scrotum/
70. vulva\*.tw.
71. scrot\*.tw.
72. (labium or labia).tw.
73. heat rash\*.tw.
74. (heat adj2 rash\*).tw.
75. Dermatitis, Allergic Contact/
76. ((diaper\* or napkin\* or nappy or nappies or perine\*) adj2 (dermat\* or erythema\* or rash\* or wet\*)).tw.
77. (moist\* adj2 (sore\* or ulcer\* or damag\* or wound\* or injur\* or lesion\* or skin)).tw.
78. ((decubitus or pressure or bed) adj2 (sore\* or ulcer\*)).tw.
79. bedsore\*.tw.
80. or/35-79
81. 24 and 80
82. exp Skin Care/
83. hygiene/
84. dermatologic agents/ or zinc oxide/ or emollients/ or mineral oil/ or petrolatum/ or simethicone/
85. surface-active agents/ or soaps/
86. Ointments/

87. exp Detergents/
88. pharmaceutic aids/ or ointment bases/ or petrolatum/ or pharmaceutical vehicles/ or propylene glycol/
89. pharmaceutical vehicles/ or propylene glycol/ or excipients/ or octoxynol/ or poloxamer/ or polysorbates/ or tragacanth/ or tromethamine/
90. skincar\*.tw.
91. skin care.tw.
92. (skin adj2 (regime\* or protocol\* or program\*)).tw.
93. (skin adj2 clean\*).tw.
94. (skin adj2 moistur\*).tw.
95. (skin adj2 protect\*).tw.
96. (moisture adj2 barrier\*).tw.
97. (skin adj2 (product or products)).tw.
98. (perine\* adj2 clean\*).tw.
99. washcloth\*.tw.
100. barrier cloth\*.tw.
101. (wash adj2 cloth\*).tw.
102. exp Oils/
103. (skin adj2 (health or integrity or restor\* or maintain\*)).tw.
104. (skin adj2 manag\*).tw.
105. Baths/
106. (skin adj2 wash\*).tw.
107. shower\*.tw.
108. or/82-107
109. 81 and 108
110. 34 or 109
111. remove duplicates from 110
112. cochrane incontinence group.gc.
113. 111 not 112

### 3 CINAHL search strategy

**CINAHL (on EBSCO)** covering from inception (December 1981) to 20150527 (entry date) was searched on 28 May 2015 using the following search strategy:

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#	Query
S112	S27 OR S41 OR S111
S111	S23 AND S83 AND S110
S110	S84 OR S85 OR S86 OR S87 OR S88 OR S89 OR S90 OR S91 OR S92 OR S93 OR S94 OR S95 OR S96 OR S97 OR S98 OR S99 OR S100 OR S101 OR S102 OR S103 OR S104 OR S105 OR S106 OR S107 OR S108 OR S109
S109	AB shower*
S108	TI shower*
S107	(MH "Bathing and Baths") OR (MH "Self-Care Assistance: Bathing-Hygiene (Iowa NIC)") OR (MH "Bathing-Hygiene Self Care Deficit (NANDA)") OR (MH "Bathing-Hygiene Deficit (Saba CCC)") OR (MH "Self-Care: Bathing (Iowa NOC)") OR (MH "Bathing (Iowa NIC)")
S106	(MH "Oils+")
S105	AB wash N2 cloth*
S104	TI wash N2 cloth*
S103	AB barrier N2 cloth*
S102	TI barrier N2 cloth*
S101	AB washcloth*
S100	TI washcloth*
S99	AB perine* N2 clean*
S98	TI perine* N2 clean*
S97	AB moisture N2 barrier*
S96	TI moisture N2 barrier*
S95	AB skin N2 regime* OR skin N2 protocol* OR skin N2 program* OR skin N2 clean* OR skin N2 moistur* OR skin N2 protect* OR skin N2 product OR skin N2 products OR skin N2 health OR skin N2 integrity OR skin N2 restor* OR skin N2 maintain* OR skin N2 manag* OR skin N2 wash*
S94	TI skin N2 regime* OR skin N2 protocol* OR skin N2 program* OR skin N2 clean* OR skin N2 moistur* OR skin N2 protect* OR skin N2 product OR skin N2 products OR skin N2 health OR skin N2 integrity OR skin N2 restor* OR skin N2 maintain* OR skin N2 manag* OR skin N2 wash*
S93	AB skin care
S92	TI skin care
S91	AB skincare
S90	TI skincare
S89	(MH "Propylene Glycols+")
S88	(MH "Creams") OR (MH "Ointments") OR (MH "Liniments")
S87	(MH "Surface-Active Agents+")
S86	(MH "Dermatologic Agents+")

S85	(MH "Hygiene") OR (MH "Self-Care Assistance: Bathing-Hygiene (Iowa NIC)") OR (MH "Bathing-Hygiene Self Care Deficit (NANDA)") OR (MH "Bathing-Hygiene Deficit (Saba CCC)") OR (MH "Self-Care: Hygiene (Iowa NOC)")
S84	(MH "Skin Care") OR (MH "Skin Care (Saba CCC)") OR (MH "Skin Care: Topical Treatments (Iowa NIC)") OR (MH "Perineal Care")
S83	S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69 OR S70 OR S71 OR S72 OR S73 OR S74 OR S75 OR S76 OR S77 OR S78 OR S79 OR S80 OR S81 OR S82
S82	AB bed N2 sore* OR bed N2 ulcer*
S81	TI bed N2 sore* OR bed N2 ulcer*
S80	AB pressure N2 sore* OR pressure N2 ulcer*
S79	TI pressure N2 sore* OR pressure N2 ulcer*
S78	AB decubitus N2 sore* OR decubitus N2 ulcer*
S77	TI decubitus N2 sore* OR decubitus N2 ulcer*
S76	AB moist* N2 sore* OR moist* N2 ulcer* OR moist* N2 damag* OR moist* N2 wound* OR moist* N2 injur* OR moist* N2 lesion* OR moist* N2 skin
S75	TI moist* N2 sore* OR moist* N2 ulcer* OR moist* N2 damag* OR moist* N2 wound* OR moist* N2 injur* OR moist* N2 lesion* OR moist* N2 skin
S74	AB perine* N2 rash* OR perine* N2 wet*
S73	TI perine* N2 rash* OR perine* N2 wet*
S72	AB nappies N2 dermatit* OR nappies N2 rash* OR nappies N2 wet*
S71	TI nappies N2 dermatit* OR nappies N2 rash* OR nappies N2 wet*
S70	AB nappy N2 dermatit* OR nappy N2 rash* OR nappy N2 wet*
S69	TI nappy N2 dermatit* OR nappy N2 rash* OR nappy N2 wet*
S68	AB napkin* N2 dermatit* OR napkin* N2 rash* OR napkin* N2 wet*
S67	TI napkin* N2 dermatit* OR napkin* N2 rash* OR napkin* N2 wet*
S66	AB diaper* N2 dermatit* OR diaper* N2 rash* OR diaper N2 wet*
S65	TI diaper* N2 dermatit* OR diaper* N2 rash* OR diaper N2 wet*
S64	AB bedsore*
S63	TI bedsore*
S62	AB rash* N2 heat
S61	TI rash* N2 heat
S60	AB dermatit* N2 contact OR dermatit* N2 contact
S59	TI dermatit* N2 contact OR dermatit* N2 contact
S58	AB rash* N2 cuticle
S57	TI rash* N2 cuticle

S56	AB epiderm* N2 loss* OR epiderm* N2 red* OR epiderm* N2 blister* OR epiderm* N2 bull* OR epiderm* N2 perine* OR epiderm* N2 barrier* OR epiderm* N2 loss* OR epiderm* N2 inflam* OR epiderm* N2 integrity OR epiderm* N2 rash*
S55	TI epiderm* N2 loss* OR epiderm* N2 red* OR epiderm* N2 blister* OR epiderm* N2 bull* OR epiderm* N2 perine* OR epiderm* N2 barrier* OR epiderm* N2 loss* OR epiderm* N2 inflam* OR epiderm* N2 integrity OR epiderm* N2 rash*
S54	AB cutaneous N2 loss* OR cutaneous N2 red* OR cutaneous N2 blister* OR cutaneous N2 bull* OR cutaneous N2 perine* OR cutaneous N2 barrier* OR cutaneous N2 loss* OR cutaneous N2 inflam* OR cutaneous N2 integrity OR cutaneous N2 rash*
S53	TI cutaneous N2 loss* OR cutaneous N2 red* OR cutaneous N2 blister* OR cutaneous N2 bull* OR cutaneous N2 perine* OR cutaneous N2 barrier* OR cutaneous N2 loss* OR cutaneous N2 inflam* OR cutaneous N2 integrity OR cutaneous N2 rash*
S52	AB erythema*
S51	TI erythema*
S50	AB skin N2 loss* OR skin N2 red* OR skin N2 blister* OR skin N2 bull* OR skin N2 perine* OR skin N2 erod* OR skin N2 erosion* OR skin N2 barrier* OR skin N2 rash* OR skin N2 damag* OR skin N2 lesion*
S49	TI skin N2 loss* OR skin N2 red* OR skin N2 blister* OR skin N2 bull* OR skin N2 perine* OR skin N2 erod* OR skin N2 erosion* OR skin N2 barrier* OR skin N2 rash* OR skin N2 damag* OR skin N2 lesion*
S48	AB skin N2 inflam*
S47	TI skin N2 inflam*
S46	AB skin N2 integrity
S45	TI skin N2 integrity
S44	AB pressure N2 ulcer
S43	TI pressure N2 ulcer
S42	(MH "Pressure Ulcer") OR (MH "Pressure Ulcer Stage 4 Care (Saba CCC)") OR (MH "Pressure Ulcer Stage 3 Care (Saba CCC)") OR (MH "Pressure Ulcer Stage 2 Care (Saba CCC)") OR (MH "Pressure Ulcer Stage 1 Care (Saba CCC)") OR (MH "Pressure Ulcer Care (Saba CCC)") OR (MH "Pressure Ulcer Prevention (Iowa NIC)") OR (MH "Pressure Ulcer Care (Iowa NIC)")
S41	S23 AND S40
S40	S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39
S39	AB perine* N2 dermatitis*
S38	TI perine* N2 dermatitis*
S37	AB macerat* N2 skin*
S36	TI macerat* N2 skin*
S35	AB moisture N2 lesion*
S34	TI moisture N2 lesion*
S33	AB incontinen* N2 lesion*
S32	TI incontinen* N2 lesion*

S31	AB incontinen* N25 skin
S30	TI incontinen* N25 skin
S29	AB incontinen* N25 dermatitis
S28	TI incontinen* N25 dermatitis
S27	S23 AND S26
S26	S24 OR S25
S25	(MH "Diaper Rash")
S24	(MH "Dermatitis, Perineal")
S23	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22
S22	TI ( singl* N25 blind* OR singl* N25 mask* OR doubl* N25 blind* or doubl* N25 mask* OR trebl* N25 blind* OR trebl* N25 mask*OR tripl* N25 blind* OR tripl* N25 mask* ) or AB ( singl* N25 blind* OR singl* N25 mask* OR doubl* N25 blind* or doubl* N25 mask* OR trebl* N25 blind* OR trebl* N25 mask*OR tripl* N25 blind* OR tripl* N25 mask* )
S21	(MH "Comparative Studies")
S20	(MH "Clinical Research+")
S19	(MH "Static Group Comparison")
S18	(MH "Quantitative Studies")
S17	(MH "Crossover Design") or (MH "Solomon Four-Group Design")
S16	(MH "Factorial Design")
S15	(MH "Community Trials")
S14	(MH "Random Sample")
S13	TI balance* N2 block* or AB balance* N2 block*
S12	TI "latin square" or AB "latin square"
S11	TI factorial or AB factorial
S10	TI clin* N25 trial* or AB clin* N25 trial*
S9	(MH "Study Design")
S8	(AB random*) OR (TI random*)
S7	(AB placebo*) OR (TI placebo*)
S6	(MH "Placebos")
S5	(PT Clinical Trial) OR (PT "randomized controlled trial")
S4	(MH "Clinical Trials+")
S3	MH (random assignment) OR (crossover design)
S2	cross-over
S1	crossover

## 4 Web of Science (WoS) search strategy

**Web of Science (on Web of Knowledge)** – covering from inception of each component database to the most recent records available - was searched on 28 May 2015 using the search strategy given below. The search was limited to the WoS Core Collection

Set	
#42	#40 OR #22 <b>Refined by: Databases:</b> ( WOS ) <i>Timespan=All years</i> <i>Search language=Auto</i>
#41	#40 OR #22 <i>Timespan=All years</i> <i>Search language=Auto</i>
#40	#39 AND #33 AND #5 <i>DocType=All document types; Language=All languages;</i>
#39	#38 OR #37 OR #36 OR #35 OR #34 <i>DocType=All document types; Language=All languages;</i>
#38	<b>TOPIC:</b> (Oils or bath* OR shower* OR hygiene OR zinc oxide OR emollients OR mineral oil OR petrolatum OR simethicone OR soap* OR ointment* OR detergent*) <i>DocType=All document types; Language=All languages;</i>
#37	<b>TOPIC:</b> ((wash OR barrier) NEAR/2 cloth) <i>DocType=All document types; Language=All languages;</i>
#36	<b>TOPIC:</b> (washcloth* OR skincar*) <i>DocType=All document types; Language=All languages;</i>
#35	<b>TOPIC:</b> ((skin NEAR/2 (care OR regime* OR protocol* OR program* OR clean* OR moistur* OR protect* OR product OR products OR health OR integrity OR restor* OR maintain* OR manag* OR wash*))) <i>DocType=All document types; Language=All languages;</i>
#34	<b>TOPIC:</b> (perine* NEAR/2 clean*) <i>DocType=All document types; Language=All languages;</i>
#33	#32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 <i>DocType=All document types; Language=All languages;</i>
#32	<b>TOPIC:</b> (bedsore*) <i>DocType=All document types; Language=All languages;</i>
#31	<b>TOPIC:</b> ((decubitus OR pressurre OR bed) NEAR/2 (sore* OR ulcer*)) <i>DocType=All document types; Language=All languages;</i>
#30	<b>TOPIC:</b> (moist* NEAR/2 (sore* OR ulcer* OR damag* OR wound* OR injur* OR lesion* or skin)) <i>DocType=All document types; Language=All languages;</i>
#29	<b>TOPIC:</b> ((diaper* OR napkin* OR nappy OR nappies OR perine*) NEAR/2 (dermat* OR erythema* OR rash* OR wet*)) <i>DocType=All document types; Language=All languages;</i>

#28	<b>TOPIC:</b> (dermatit* NEAR/2 (contact OR irrit*)) <i>DocType=All document types; Language=All languages;</i>
#27	<b>TOPIC:</b> (rash* NEAR/2 (epiderm* OR cutaneous OR cuticle)) <i>DocType=All document types; Language=All languages;</i>
#26	<b>TOPIC:</b> (erythema*) <i>DocType=All document types; Language=All languages;</i>
#25	<b>TOPIC:</b> (epiderm* NEAR/2 (integrity OR inflam* OR loss* OR red* OR blister* OR bull* OR perine* OR erod* OR erosion* OR barrier* OR rash* OR lesion* OR damag*)) <i>DocType=All document types; Language=All languages;</i>
#24	<b>TOPIC:</b> (cutaneous NEAR/2 (integrity OR inflam* OR loss* OR red* OR blister* OR bull* OR perine* OR erod* OR erosion* OR barrier* OR rash* OR lesion* OR damag*)) <i>DocType=All document types; Language=All languages;</i>
#23	<b>TOPIC:</b> (skin NEAR/2 (integrity OR inflam* OR loss* OR red* OR blister* OR bull* OR perine* OR erod* OR erosion* OR barrier* OR rash* OR lesion* OR damag*)) <i>DocType=All document types; Language=All languages;</i>
#22	#21 AND #5 <i>DocType=All document types; Language=All languages;</i>
#21	#20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 <i>DocType=All document types; Language=All languages;</i>
#20	<b>TOPIC:</b> (diaper rash) <i>DocType=All document types; Language=All languages;</i>
#19	<b>TOPIC:</b> (perine* NEAR/2 dermatitis*) <i>DocType=All document types; Language=All languages;</i>
#18	<b>TOPIC:</b> (macerat* NEAR/2 skin*) <i>DocType=All document types; Language=All languages;</i>
#17	<b>TOPIC:</b> (moisture NEAR/2 lesion*) <i>DocType=All document types; Language=All languages;</i>
#16	<b>TOPIC:</b> (incontinen* NEAR/2 lesion*) <i>DocType=All document types; Language=All languages;</i>
#15	<b>TOPIC:</b> (dermatological AND (pressure near/2 ulcer*)) <i>DocType=All document types; Language=All languages;</i>
#14	<b>TOPIC:</b> (emollient* AND decubit*) <i>DocType=All document types; Language=All languages;</i>
#13	<b>TOPIC:</b> ((mineral near/2 oil*) AND decubit*) <i>DocType=All document types; Language=All languages;</i>
#12	<b>TOPIC:</b> (dermatological AND decubit*) <i>DocType=All document types; Language=All languages;</i>
#11	<b>TOPIC:</b> (petrolatum AND decubit*) <i>DocType=All document types; Language=All languages;</i>
#10	<b>TOPIC:</b> (petrolatum AND (pressure near/2 ulcer*)) <i>DocType=All document types; Language=All languages;</i>

#9	<b>TOPIC:</b> ((mineral near/2 oil*) AND (pressure near/2 ulcer*)) <i>DocType=All document types; Language=All languages;</i>
#8	<b>TOPIC:</b> (emollient* AND (pressure near/2 ulcer*)) <i>DocType=All document types; Language=All languages;</i>
#7	<b>TOPIC:</b> (incontinence NEAR/25 skin) <i>DocType=All document types; Language=All languages;</i>
#6	<b>TOPIC:</b> (incontinence NEAR/25 dermatitis) <i>DocType=All document types; Language=All languages;</i>
#5	#4 OR #3 OR #2 OR #1 <i>DocType=All document types; Language=All languages;</i>
#4	<b>TOPIC:</b> (((singl* OR doubl* OR trebl* OR tripl*) SAME (blind* OR mask*))) <i>DocType=All document types; Language=All languages;</i>
#3	<b>TOPIC:</b> ((clin* SAME trial*)) <i>DocType=All document types; Language=All languages;</i>
#2	<b>TOPIC:</b> ((placebo*)) <i>DocType=All document types; Language=All languages;</i>
#1	<b>TOPIC:</b> ((random*)) <i>DocType=All document types; Language=All languages;</i>