

THE JOANNA BRIGGS INSTITUTE

Systematic Review Protocol

Title: Skin Care Provided in an Aged Care Facility

Centre: Australian Centre for Evidence Based Residential Aged Care

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General Information

How do we assess best practice?

Best practice in Nursing aims to provide care determined on the basis of the best available evidence. Systematic reviews are the tool we use to identify what this evidence is as they use explicit, systematic methods to limit bias and reduce the effect of chance in the review, and therefore provide more reliable and consistent results upon which to draw conclusions (Clarke & Oxman 2000).

“Systematic reviews provide information about the effectiveness of interventions by identifying, appraising, and summarising the results of otherwise unmanageable quantities of research.” (Khan et al 2001). The primary focus of systematic reviews in medicine is to integrate empirical research for the purpose of creating generalisations and thus to provide a rational basis for health care decision making (Mulrow et al 1997; Cooper & Hedges 1994).

The key components of a systematic review include: (1) the development of a specific research question or hypothesis (2) a transparent methodical process defined *a priori* (i.e. a review protocol) (3) an exhaustive search for relevant primary research on the topic (4) the critical appraisal of this research (5) an attempt to answer the research question and to resolve conflicts in the literature, and (6) the identification of issues central to future research on the topic (Clarke & Oxman 2000; Mulrow et al 1997; Cooper & Hedges 1994)

Aim of the Protocol

The primary function of the Protocol is to guide the assessment or review of “skin care provided in an aged care facility”. This Protocol is a synthesis of systematic review methodology, as provided by the evaluators, and clinical information on viscosupplementation as provided by the Review Panel members. The structure of the assessment report will be as follows:

- Background
 - The procedure
 - Intended purpose
 - Clinical need/burden of disease
 - Existing procedures
 - Comparator (s)
- Approach to assessment
 - Review of literature
 - Expert advice
- Results of assessment

- Is it safe?
- Is it effective?
- Conclusions
- Safety
- Effectiveness

- Recommendation(s)

Evaluators

Consultant reviewer: Mr. Brent Hodgkinson

Assistant reviewer: Dr. Kim Nichols

Role of the Review Panel

Review Panel members should consider the assessment process outlined in the draft protocol document from their perspective as clinical or content experts.

- Are the objectives and research questions appropriate?
- Are the inclusion criteria relevant?
- Are the search strategies comprehensive?

The protocol will only be finalised after the Review Panel has provided input. Once finalised, the protocol for the assessment should not be altered as it provides the structure for the entire review/assessment process.

The Review Panel collaborates with the evaluators throughout the assessment process until a final version of the Systematic Review is produced.

Review Panel membership

Professor Rhonda Nay – Director - ACEBAC

Mr Bill McGuinness - LaTrobe University

Mr Raj Sivaraj - Pharmacist - Bundoora Extended Care Centre

Ms Helen Sheehan - Chief Dietician - Northern Health

Dr Wendy MacDonald - La Trobe University

Dr Phillip Street - Geriatrician - Bundoora Extended Care Centre

Ms Catherine Jones - Physiotherapist - Royal Melbourne Hospital

Ms Cathie Edgar - Nurse Educator -Bundoora Extended Care Centre

Ms Christina Nielsen - Nurse Educator - Melbourne Extended Care Centre

Bernie Hadfield - Stomal Therapist - Alfred Hospital-

Ms. Samantha Nugent – Research Officer - ACEBAC

Introduction

Rationale for Assessment

The Australian Centre for Evidence Based Aged Care (ACEBAC) has requested that a systematic review of skin care in older adults who reside in aged care facilities, be performed in order to identify best practice.

Background

In the 2001 Australian census it was revealed that adults aged 65 years and over constituted 12.6 percent of the population up from 12.1 percent in 1996 (ABS 2003). It is projected that this figure will rise to 21% or 5.1 million Australians by 2031. Living arrangements in Australia in 1998 found that 6 percent (134,000) of adults aged 65 years and over were residing in nursing homes or hostels (ABS 2003). As the percentage of Australians in this age group is predicted to rise (as above) it can be expected that the number of persons living in nursing homes will also continue to increase.

Skin care

Generally, placement in a long-term care facility indicates an inability of the older person to perform all of the activities of daily living. Therefore, they may require assistance with such tasks as toileting, bathing, dressing and meal preparation. As a person ages, major physiological changes occur that require more attention.

One such area is skin care. Decreased turnover and replacement of epidermal skin cells, a thinning subcutaneous fat layer and a reduced production of protective oils (Finch 2003) are but a few of the changes that occur in ageing skin. These changes can affect the normal functions of the skin such as its role as a barrier to irritants and pathogens, temperature and water regulation (Penzer & Finch 2001).

Due to reductions in physiological and psychological functioning, some older adults in extended nursing care are susceptible to dry skin or pruritis that is estimated to be a problem in 59 to 85 percent of the elderly population (Hardy 1996). Scratching can result in inflammation and ultimately, skin damage (Penzer & Finch 2001). Incontinence, a major problem in nursing home residents can lead to skin irritation and possible breakdown (Lyder et al 1992).

Therefore it is essential that skin care management protocols be developed to maximise the skin integrity of the older person in care and reduce the likelihood of pressure sores, skin irritation and ultimately promote comfort of the older person (Penzer & Finch 2001).

While literature exists on Nurse led care of skin in older adults, to date no systematic review of this literature has been performed.

Objective

Assessment Objective

The objective of this systematic review is to determine what are the most effective and safe topical skin care regimens for maintaining skin integrity, in an aged population in long term care.

Research Questions

What are the best methods of providing skin care in an elderly population in long term care prevent or reduce the occurrence of:

1. skin tears?
2. dry skin and irritation?
3. Development of open sores (not pressure sores)

Effectiveness

This review is about preventing the occurrence of adverse skin conditions in an elderly institutionalised population. The inclusion criteria are outlined in Box 1.

Box 1 Inclusion criteria for effectiveness of skin care regimens

Patients: Adults 65 years of age or over residing in an aged care facility. If these studies are not available, studies using adults aged 65 years and over who are hospitalised or in long term care in the community will be considered.

Intervention: Any topical intervention or program that aims to prevent the development of adverse skin conditions (not repair) in older institutionalised adults.

Comparators: The most appropriate comparators would be a no care protocol, or existing practice related to maintaining skin integrity.

Outcomes: Incidence of adverse skin conditions such as rash, skin irritation, haematoma or tears during the treatment or control, study period. Pressure ulcer prevention will not be considered. Patient satisfaction will also be considered.

Eligible Study Designs: To determine the effectiveness of an intervention such as a care regimen randomised controlled trials (RCT) or systematic reviews of RCT would be the methods of choice. However, in the absence of RCT, controlled trials will also be considered. Other research designs will be considered for inclusion in a narrative summary to document the range of approaches that have been investigated.

Language: Searches will include all English and foreign language publications. Assessment for inclusion of foreign language publications will be based on the English language abstract, where available.

Safety

Effectiveness is not the only consideration in providing a medical treatment. The inclusion criteria for the safety of any skin care regimens are outlined in Box 2.

Box 2 Inclusion criteria for evaluating the safety of skin care regimens

Patients: Adults 65 years of age or over residing in an aged care facility. If these studies are not available, studies using adults aged 65 years and over who are hospitalised or in long term care in the community will be considered.

Intervention: Any non-medical intervention or program that aims to maintain or improve the integrity of skin in older adults.

Comparators: The most appropriate comparators would be a no care protocol, or existing practice related to maintaining skin integrity.

Outcomes: Adverse physical health outcomes associated with the treatment/management options.

Eligible Study Designs: Randomised or non-randomised controlled trials, cohort studies, registers, or systematic reviews of these study designs. In the event that the evidence-base is lacking these study designs, case-control or cross-sectional studies will be acceptable, although low quality, alternatives.

Language: Searches will include all English and foreign language publications. Assessment for inclusion of foreign language publications will be based on the English language abstract, where available.

Search Strategy

Sources of Prevalence Data

The population of Australian adults aged 65 years and over residing in nursing homes or extended care facilities will be determined from the most recent Australian census data (Australian Bureau of Statistics). Prevalence of adverse skin conditions will be determined where possible from existing Australian hospital and general practitioner morbidity databases.

Literature Sources

Bibliographic Databases

- PubMed (NLM) : 1966 – 4/2003
- Embase: 1966 – 4/2003
- CINAHL (SilverPlatter): 1966 – 4/2003
- Current Contents: 1993 – 4/2003
- Cochrane Library: 1966 – 2/2003
 - Cochrane Database of Systematic Reviews (CDSR)
 - Database of Abstracts of Reviews of Effectiveness (DARE)
 - The Cochrane Controlled Trials Register (CCTR)
 - The Health Technology Assessment Database (HTA)
 - NHS Economic Evaluation Database (NHS EED)
- Web of Science: 1995 – 12/2002
- Science Citation Index Expanded
- ProceedingsFirst: 1993 – 12/2002

Internet

- Scirus – for Scientific Information Only (<http://www.scirus.com>) : 1973-12/2002
- Trip database <http://www.tripdatabase.com>

HTA Sources (English language)

GENERAL

The following general databases of health technology assessment reports will be searched up until 4/2003:

- International Society of Technology Assessment in Health Care
<http://www.istahc.org/en/welcome.html>
- International Network for Agencies for Health Technology Assessment
<http://www.inahta.org/> [the same HTA database that is held in Cochrane]
- National Library of Medicine Health Services / Technology Assessment Text
<http://text.nlm.nih.gov/>
- National Library of Medicine Locator Plus database
<http://locatorplus.gov>

More recent listings of reports will be located and searched at the websites of health technology assessment agencies up until 4/2003:

AUSTRALIA

- Centre for Clinical Effectiveness (Monash University, Australia)
<http://www.med.monash.edu.au/healthservices/cce/evidence/>

AUSTRIA

- Institute of Technology Assessment / HTA unit
<http://www.oeaw.ac.at/ita/e1-3.htm>

CANADA

- Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé (AETMIS)
<http://www.aetmis.gouv.qc.ca/en/index.htm>
- Alberta Heritage Foundation for Medical Research (AHFMR)
<http://www.ahfmr.ab.ca/publications.html>
- Canadian Coordinating Office for Health Technology Assessment (CCHOTA)
<http://www.ccohta.ca/newweb/pubapp/pubs.asp>
- Canadian Health Economics Research Association (CHERA/ACRES) – Cabot database
<http://www.mycabot.ca>
- Centre for Health Services and Policy Research (CHSPR), University of British Columbia
<http://www.chspr.ubc.ca>
- Health Utilities Index (HUI)
<http://www.fhs.mcmaster.ca/hug/index.htm>
- Institute for Clinical and Evaluative Studies (ICES)
<http://www.ices.on.ca>

DENMARK

- Danish Institute for Health Technology Assessment (DIHTA)
http://www.dihta.dk/publikationer/index_uk.asp

FINLAND

- FINOHTA <http://www.stakes.fi/finohta/e/>

FRANCE

- L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)
<http://www.anaes.fr/>

GERMANY

- German Institute for Medical Documentation and Information (DIMDI) / HTA <http://www.dahta.dimdi.de/>
- German Scientific Working Group of Technology Assessment
- [http://www.epi.mh-hannover.de/\(eng\)/hta.html](http://www.epi.mh-hannover.de/(eng)/hta.html)

THE NETHERLANDS

- Health Council of the Netherlands Gezondheidsraad
<http://www.gr.nl/engels/welcome/frameset.htm>

NEW ZEALAND

- New Zealand Health Technology Assessment (NZHTA)
<http://nzhta.chmeds.ac.nz/>

NORWAY

- Norwegian Centre for Health Technology Assessment (SMM)
<http://www.oslo.sintef.no/smm/Publications/Engsmdrag/FramesetPublications.htm>

SPAIN

- Agencia de Evaluación de Tecnologías Sanitarias, Instituto de Salud "Carlos III"/Health Technology Assessment Agency (AETS)
<http://www.isciii.es/aets/cdoc.htm>
- Catalan Agency for Health Technology Assessment (CAHTA)
<http://www.aatm.es/cgi-bin/frame.pl/ang/pu.html>

SWEDEN

- Swedish Council on Technology Assessment in Health Care (SBU)
<http://www.sbu.se/admin/index.asp>

SWITZERLAND

- Swiss Network on Health Technology Assessment (SNHTA)
<http://www.snhta.ch/>

UNITED KINGDOM

- Health Technology Board for Scotland <http://www.htbs.org.uk/>
- National Health Service Health Technology Assessment (UK) / National Coordinating Centre for Health Technology Assessment (NCCHTA)
<http://www.hta.nhsweb.nhs.uk/>
- University of York NHS Centre for Reviews and Dissemination (NHS CRD)
<http://www.york.ac.uk/inst/crd/>
- National Institute for Clinical Excellence (NICE)
<http://www.nice.org.uk/index.htm>

UNITED STATES

- Agency for Healthcare Research and Quality (AHRQ)
<http://www.ahrq.gov/clinic/techix.htm>
- U.S. Dept. of Veterans Affairs Technology Assessment Program (VATAP)
http://www.va.gov/resdev/prt/pubs_individual.cfm?webpage=pubs_ta_reports.htm

Hand Searching

For completeness, the most recent issues of several aged care medical and nursing journals will be searched. These will include:

- Gerontologist
- International Journal of Gerontologic Nursing
- Geriatric Nursing
- Australasian Journal of Nursing
- Journal of Clinical Nursing
- Journal of Tissue Viability
- International Journal of Wound Care

Pearling

All included articles will have their reference lists searched for additional relevant source material.

Search Strategies

The following search strategy has been developed for PubMed . Similar strategies will be used for the different bibliographic databases, with the same text words being used along with the relevant alternatives to MeSH (i.e. EmTree headings in EMBASE).

Table x PubMed search strategy for skin care in the elderly adult in long term care

Search category	Search terms
MeSH	Adult; homes for the aged; housing for the elderly; long term care; health services for the aged; geriatric nursing; skin care, safety, nutrition
Title or abstract terms	Adult*; aged; senior*; nursing home*; long term care; geriatric*; skin*

Validity Assessment

The evidence presented in the selected studies will be assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council (NHMRC) (NHMRC 2000).

These dimensions (Table 4) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of their determination.

Table 4 Evidence dimensions

Type of evidence	Definition
Strength of the evidence	The study design used, as an indicator of the degree to which bias has been eliminated by design.*
Level	The methods used by investigators to minimise bias within a study design.
Quality	The <i>p</i> -value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Statistical precision	
Size of effect	The distance of the study estimate from the “null” value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence.

Level of evidence

Levels of evidence differ in terms of the hierarchy, depending on the type of research question being asked. Studies assessing the effectiveness of interventions (such as screening or therapy/management) will be assessed using the NHMRC levels of evidence (Table 5).

Table 5 Designations of levels of evidence for assessing intervention studies*

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test/post-test

*Modified from (NHMRC 2000)

Quality of evidence

The appraisal of systematic reviews will be performed using a checklist developed by the NHS Centre for Reviews and Dissemination (Khan et al 2001). This is a generic checklist that allows for the appraisal of systematic reviews that incorporate study designs other than RCTs (Appendix A). A “quality score” will be approximated from this checklist by attaching a point to each criterion that is met by the systematic review.

The appraisal of intervention studies will be undertaken using a checklist developed by Downs and Black (Appendix A) (Downs & Black 1998) and modified by the Health Technology Assessment Unit, Department of Public Health, University of Adelaide. This checklist is suitable for trials and cohort studies and has been psychometrically assessed to have overall high internal consistency, good test-re-test and inter-rater reliability, and high criterion validity. However, the checklist will be modified by dropping the five items relating to the power subscale and evaluate power independently (Coster et al 2000). Therefore, the checklist will produce an overall Quality Index score (total=27), along with subscale scores (Reporting, External Validity, Bias and Confounding). Information on specific methodological components shown empirically to impact on treatment effect sizes are also included in this checklist – specifically, concealment of allocation, blinding, and completeness of data (Juni et al 1999; Moher et al 1998; Schulz et al 1995).

Size of effect and relevance of evidence

For intervention studies, rank scoring methods will be used to determine the clinically important benefit of the effect size, as well as the clinical relevance of the outcome being assessed (NHMRC 2000). See Appendix A.

Data Extraction and Analysis

A flow chart will be used to describe the selection process for all the included articles.

Standardised protocols and outcome definitions developed by the Joanna Briggs Institute for Evidence based Nursing and Midwifery will be used by the assessor to extract the data.

A study profile will be developed for each study – outlining the institution, author, publication year, methodology used, type of intervention and comparator interventions, the study population characteristics and the follow-up period.

Information on each of the relevant outcomes will also be extracted and tabulated – including numerator and denominator information and summary measures of effect, where appropriate.

Meta-analyses of either randomised or non-randomised controlled trials, or cohort studies will be conducted, where appropriate, and tested for heterogeneity and publication bias. Sensitivity analyses (particularly analysing study quality) and stratification on known confounders will occur where necessary.

Where meta-analysis cannot be conducted, a qualitative synthesis of the data will be undertaken.

References

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- Khan, K. S., Ter Riet, G. et al (2001). *Undertaking systematic reviews of research on effectiveness. CRD's guidance for those carrying out or commissioning reviews*, NHS Centre for Reviews and Dissemination, University of York, York.
- Lyder, C. H., Clemes-Lowrance, C. et al (1992). 'Structured skin care regimen to prevent perineal dermatitis in the elderly', *Journal of ET Nursing*, 19 (1), 12-16.
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NHMRC (2000). *How to use the evidence: assessment and application of scientific evidence*, National Health and Medical Research Council, Canberra.

Penzer, R. & Finch, M. (2001). 'Promoting healthy skin in older people', *Nursing Standard*, 15 (34), 46-52; quiz 54-45.

Schulz, K. F., Chalmers, I. et al (1995). 'Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials', *Journal of the American Medical Association*, 273 (5), 408-412.

Appendix A Critical Appraisal Checklists

Systematic review critical appraisal checklist

Source: (Khan et al 2001)

Title of assessment:

Title of systematic review:

Author(s):

Year:

Comparators:

Score : /6

1. What is the review's objective?

What were the population/participants, interventions, outcomes and study designs?

2. What sources were searched to identify primary studies?

What sources (e.g. databases) were searched and were any restrictions by date, language and type of publication used? Were other strategies used to identify research?

3. What were the inclusion criteria and how were they applied?

4. What criteria were used to assess the quality of primary studies and how were they applied?

5. How were the data extracted from the primary studies?

6. How were the data synthesised?

How were differences between studies investigated?

How were the data combined? Was it reasonable to combine the studies?

What were the summary results of the review?

Do the conclusions flow from the evidence reviewed?

Rank scoring for appraising the clinical importance of benefit/harm

Source: (National Health and Medical Research Council 2000)

Title of review:

Title of study:

Author(s):

Year:

Comparators:

Clinically important effect:

Rank Score : **/4**

Ranking	Clinical importance of benefit/harm
1	A clinically important benefit for the full range of plausible estimates. The confidence limit closest to the measure of no effect (the 'null') rules out a clinically unimportant effect of the intervention.
2	The point estimate of effect is clinically important BUT the confidence interval includes clinically unimportant effects.
3	The confidence interval does not include any clinically important effects.
4	The range of estimates defined by the confidence interval includes clinically important effects BUT the range of estimates defined by the confidence interval is also compatible with no effect, or a harmful effect.

Rank scoring for classifying the relevance of evidence

Source: (National Health and Medical Research Council 2000)

Title of review:

Title of study:

Author(s):


Year:

Comparators:

Rank Score : /5

Ranking	Relevance of the evidence
1	Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.
2	Evidence of an effect on a surrogate outcome that has been shown to be predictive of patient-relevant outcomes for the same intervention.
3	Evidence of an effect on proven surrogate outcomes but for a different intervention.
4	Evidence of an effect on proven surrogate outcomes but for a different intervention and population.
5	Evidence confined to unproven surrogate outcomes.

Checklist for appraising the quality of intervention studies

 <p>THE UNIVERSITY OF ADELAIDE AUSTRALIA</p>	<h3>STUDY QUALITY ASSESSMENT CHECKLIST</h3> <p>Suitable for trials, cohorts and case-control studies assessing interventions (Downs and Black (1998)–adapted for this assessment)</p>
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Author(s):
Institution(s):
Year:
Study Design:
Comparators:

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

y e s	
n o	

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*

If the main outcomes are first mentioned in the Results section, the question should be answered 'no'.

y e s	1
n o	0

3. *Are the characteristics of the patients included in the study clearly described?*

In cohort studies and trials, inclusion and/or exclusion criteria should be given.

y e s	1
n o	0

4. *Are the interventions of interest clearly described?*

Interventions that are to be compared should be clearly described.

y e s	1
n o	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*

y e s	2
p a r t i a l l y	1
n o	0

6. *Are the main findings of the study clearly described?*
Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions (This question does not cover statistical tests which are considered below).

y e s	1
n o	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered 'yes'.

y e s	1
n o	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
This should be answered 'yes' if the study demonstrates that there was a comprehensive attempt to measure adverse events.

y e s	1
n o	0

9. *Have the characteristics of patients lost to follow-up been described?*

This should be answered 'yes' where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered 'no' where a study does not report the number of patients lost to follow-up.

y e s	1
n o	0

10. *Have the actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes, except where the probability value is less than 0.001?*

y e s	1
n o	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*

The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as 'unable to determine'.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*

For the question to be answered 'yes' the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered 'no' if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0

unable to determine	0
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Internal validity - Bias

14. *Was an attempt made to blind study subjects to the intervention they have received?*
For studies where the patients would have no way of knowing which intervention they received, this should be answered 'yes'.

yes	1
no	0
unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

yes	1
no	0
unable to determine	0

16. *If any of the results of the study were based on "data dredging", was this made clear?*
Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer 'yes'.

yes	1
no	0
unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients?*
Where follow-up was the same for all study patients the answer should be 'yes'. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be 'yes'. Studies where differences in follow-up are ignored should be answered 'no'.

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*
The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered 'yes'. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered 'yes'.

yes	1
no	0
unable to determine	0

19. *Was compliance with the intervention/s reliable?*
Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered 'no'. For studies where the

effect of any misclassification was likely to bias any association to the null, the question should be answered 'yes'.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, the question should be answered 'yes'. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered 'yes'.

yes	1
no	0
unable to determine	0

Internal validity – Confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) recruited from the same population?*

For example, patients for all comparison groups should be selected from the same hospital. The question should be answered 'unable to determine' where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) recruited over the same period of time?*

For a study which does not specify the time period over which the patients were recruited, the question should be answered as 'unable to determine'.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*

Studies which state that subjects were randomised should be answered 'yes' except where method of randomisation is unknown or would not ensure random allocation. For example, alternate allocation would score 'no' because it is predictable.

yes	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

All non-randomised studies should be answered 'no'. If assignment was concealed from patients but not from staff, it should be answered 'no'.

yes	1
no	0
unable to determine	0

25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

This question should be answered 'no' for trials if: the main conclusions of the study were based on analyses of treatment rather than intention-to-treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as 'no'.

yes	1
no	0
unable to determine	0

26. Were losses of patients to follow-up taken into account?

If the number of patients lost to follow-up are not reported, the question should be answered as 'unable to determine'. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered 'yes'.

yes	1
no	0
unable to determine	0

Subscale Scores

Reporting = /11
 External validity = /3
 Bias = /7
 Confounding = /6

Total Quality Index Score = /27

Power

27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?

a. Was there enough power to detect a difference of ..%, in the outcome "...."?

sample sizes – $n_1 =$ $n_2 =$
 power=

RCT critical appraisal form: Skin care in an aged care facility

Author _____ Year _____ Record Number

Questions 1 to 4 must be answered “yes” for study to be included in the meta-analysis.

1) Were the participants randomised to study groups

yes no not clear

2) Other than the research intervention, were participants in each groups treated the same.

yes no not clear

3) Were the outcomes measured in the same manner for all participants

yes no not clear

4) Were groups comparable at entry

yes no not clear

Studies that answer no to questions 5, 6 or 7 will only be included in the systematic review if no other higher quality studies are identified available, however this must be noted in the report.

5) Was randomisation of participants blinded

yes no not clear

6) Were those assessing outcome blinded to treatment allocation (if outcome not objective such as survival or length of hospitalisation)

yes no not clear

7) Was there adequate follow-up of participants

yes no not clear
(less than 80% followed up)

Observational and descriptive studies critical appraisal form: Skin care in an aged care facility

Author _____ Year _____ Record Number

1) Is the study based on a random or pseudo-random sample?

yes no not clear N/A

2) Are the criteria for inclusion in the sample population clearly defined?

yes no not clear N/A

3) Were outcomes assessed using objective criteria?

yes no not clear N/A

4) If comparisons are being made, was there sufficient description of the groups?

yes no not clear N/A

5) Was an appropriate statistical analysis used?

yes no not clear N/A

Data extraction form: Skin care in an aged care facility

Author Record Number

Journal

Year

Focus

Intervention Safety

Method _____

Setting _____

Participants _____

Number of Participants

Group A Group B Group C

Interventions

Intervention A _____

Intervention B _____

Intervention C _____

Intervention Outcome Measures

Outcome Description (and length of follow-up)	Scale / Measure

RCT Results

Dichotomous Data

Outcome	Treatment Group number / total number	Control Group number / total number

Continuous Data

Outcome	Treatment Group mean & SD (number)	Control Group mean & SD (number)

Authors Conclusions

Comments
