AUTHOR(S): PAPADATOU, Z., COOPER, K., KLEIN, S., MCDUFF, C. and STEINER, M.

TITLE: Effectiveness of interventions for preventing occupational irritant hand dermatitis: a quantitative systematic review protocol. [Protocol]

YEAR: 2016

Version history:

The first version of this protocol was originally made available on 2016-10-01.
This version of the protocol was originally made available on 2016-10-01.
In total, there have been zero known revisions of the protocol.

Copyright statement:

This systematic review protocol forms part of research that has been funded by ROBERT GORDON UNIVERSITY.
The protocol document was originally hosted by JBI database of systematic reviews and implementation reports and made publicly available at https://doi.org/10.11124/JBISRIR-2016-003159.

OpenAIR takedown statement:

Review title

Effectiveness of interventions for preventing occupational irritant hand dermatitis: a quantitative systematic review protocol

Authors

Zoi Papadatou[1,2]
Kay Cooper [1,2]
Susan Klein MA[2]
Colin MacDuff RMN[2]
Markus Steiner[3]
1. The Scottish Centre for Evidence-based Multi-professional Practice: a Collaborating Centre of the Joanna Briggs Institute.
2. Robert Gordon University, Aberdeen, Scotland
3. National Health Service Grampian, Aberdeen, Scotland

Corresponding author:
Zoi Papadatou
z.papadatou@rgu.ac.uk

Review question/objective

The objective of this quantitative systematic review is to identify, appraise and synthesize the best available evidence on the effectiveness of moisturizers, barrier creams, protective gloves, skin protection education, and complex interventions (a combination of two or more of the interventions listed here) in preventing Occupational Irritant Hand Dermatitis (OIHD) in wet workers, comparing each intervention to an alternative intervention or to usual care (workers regular skin care regime).The specific review questions is: What is the effectiveness of moisturizers, barrier creams, protective gloves, skin protection education, and complex interventions in preventing OIHD in wet workers?

Background

Definition, causes and epidemiology

Occupational skin disease (OSD) accounts for one fifth of all diseases reported to the United Kingdom (UK) Occupational Disease and Intelligence Network (ODIN) with Occupational Contact Dermatitis (OCD) including both Occupational Irritant Hand Dermatitis (OIHD) and Occupational Allergic Contact

Dermatitis (OACD) representing the majority of those reported.[1] Occupational Irritant Hand Dermatitis appears to be more frequent than OACD due to the different mechanism of skin damage.[2] Occupational Irritant Hand Dermatitis is caused by a skin irritant applied to the skin for sufficient time and in sufficient concentration, whereas OACD is caused by sensitizers penetrating the skin layers and provoking a chain of immunological events which soon after (usually within seven days) cause allergy.[2] The main causes of OIHD are the nature of the substance and the degree, duration and frequency of exposure, as well as factors such as under-hydration or over-hydration of the barrier layer of the skin which can determine the susceptibility of the individual.[2] The main signs of OIHD are redness, swelling, blistering, flaking, cracking and itching.[2] Clinical investigation and diagnosis of OSD includes medical examination, patch testing, prick testing, blood testing and skin biopsy.[2] The focus of this review is on the prevention of OIHD as it is more prevalent than OACD in wet workers.

The UK's Health and Safety Executive (HSE) defines wet work as: '*…Prolonged or frequent contact with water, particularly in combination with soaps and detergents, can cause dermatitis (e.g. a long time spent washing up or frequent hand washing). 'Wet work' is the term used to describe such tasks in the workplace…*'[3(para 1)] I OSD constitutes a significant public health concern in industrial countries as it is the most common occupational hazard[4] with occupational hand dermatitis being the most frequent work-related skin disease in many Western countries.[5] It is therefore a major occupational health concern in terms of clinical and economic consequences. For example it is estimated that four million working days are lost every year due to OSD in the UK.[1] Work-related skin and respiratory disease account for a significant part of the work-related ill-health (WRIH) of the UK.[6] Several European and Asian countries, as well as the United States, also keep registers of OSD. However, due to under-diagnosis and under-reporting of the disease, it has been difficult to evaluate the actual international incidence as well as the prognosis of OSD.[4]

The evidence suggests that OSD is a significant problem amongst the working population, particularly amongst healthcare workers (HCWs).[7] Intact skin on the hands and forearms is a requirement for HCWs undertaking certain roles and it reduces the risk of healthcare associated infection (HAI).[8] In addition, a number of healthcare associated tasks have the potential to result in OSD, some of which may be severe and resistant to treatment.[9] Consideration of HCWs skin and skincare is therefore important both for patient and staff health and safety. The two most common causes of OSD are working with wet hands and contact with soaps and cleaning materials.[7] The Health and Occupation Research Network (THOR) includes a scheme known as EPIDERM in which dermatologists record any new cases of OSD they come across in the UK.[7] Data available from EPIDERM between 2002 and 2013 show significant variations in incidence rates of occupational dermatitis.[7] High incidence is defined as >30 incidents per 100,000 workers per year.[7] The five occupations with the higher rates between 2004 and 2013 were: (i) florists (110 cases per 100,000 workers per year), (ii) hairdressers and barbers (88 cases per 100,000 workers per year), (iii) cooks (70 cases per 100,000 workers per year), (iv) beauticians (64 cases per

100,000 workers per year), and (v) metal working machine operatives (61 cases per 100,000 workers per year).[7] Other occupations with high incidence rates (over 30 new cases per 100,000 workers per year) include dental practitioners, nurses, dental nurses and podiatrists.[7] It is crucial to mention that the data cited above concern the reported incidents of the UK which are restricted to more severe cases and as such, are subject to a degree of underreporting.[7] Similarly in 2001 a Freedom of Information Request in the US Food and Drug Administration's Adverse Event Reporting System regarding adverse reactions to popular alcohol-based hand rubs identified only one reported case attributed to the product.[8] Recognition of OSD differs in each country and OSD reporting is subject to diverse policies and practices throughout the globe. Despite these existing differences, underreporting of OSD appears to be a recognized and common theme.

Impact

Occupational-related skin problems (including OIHD) can cause long term ill-health and have adverse career implications for all wet workers.[2,7,10] For example there are certain occupational skin diseases caused by specific substances which can result in chronic skin disease, increased risk of developing allergic dermatitis, development of inflammatory conditions such as urticaria or even ulcerative and degenerative skin diseases.[2] Furthermore, this can impact adversely on the treatment of patients and also the cost to Health Services.[1] Reliable and continuous health surveillance for individuals at risk of developing skin reactions is essential in terms of: (i) creating a framework for early detection of skin problems, and (ii) controlling for the exposure to substances which have the potential to cause harm.[2] Early intervention and assessment is crucial to achieve successful, long term outcomes for HCWs with or without pre-existing skin conditions. Brown[1] identified the high prevalence of OCD in all industries in the UK and acknowledges the health impact as well as the economic consequences. He encouraged further evaluation of preventative measures in order to reduce the prevalence of OCD. In 2008 skin diseases were listed as the second most common occupational health problem in Europe as published in the European Risk Observatory report by the European Agency for Safety and Health at Work. Occupational skin diseases were considered one of the most emerging risks related to the exposure to chemical, physical and biological risk factors with high economic costs, calculated to be five billion euros per year in the European Union (EU).[11]

Intervention strategies

Vocational rehabilitation is described as anything that assists an employee with a health condition or disability to return to, stay in, or move into work.[10] Extensive evidence supports that work is good for health and that the benefits of work to health outweigh the risks of work as well as the effects of worklessness and unemployment.[10] Keeping employees healthy at work is a balance between the health promotion and focus on work.[10] Prevention strategies, for example compliance with health and safety regulations and rehabilitation interventions, address and incorporate biopsychosocial factors to support employees to return to or stay healthy in work.[10] In occupations where there is high risk of OIHD

the prevention strategies are usually well defined. When substances have skin-damaging potential the Control of Substances Hazardous to Health Regulations (COSHH) apply in the UK, and the employer must make an assessment of the risks to any employee liable to exposure to a substance hazardous to health.[2] Recognition and registration of skin disease on a national level depends heavily on the standards and criteria used to recognize occupational disease in each of the countries within the EU. It is therefore, difficult to compare systems or information about the recognition of occupational diseases. On a global level, the International Labour Organization (ILO) continues to provide guidance via conventions and policies regarding coherent national occupational safety and health policies to promote health and improve working conditions. Conventions particular to workplace skin exposures include the application of procedures for recognition, notification and prevention.[11] Strategies to prevent OSD may include automation of processes (depending on industry and occupation), replacement of the need for employees to expose skin to irritants and/or replacement of dangerous substances (less toxic, less irritant, less allergic).[2] Other strategies for prevention of OSD include changing the employee's behaviour, for example, encouraging changes to the frequency of hand washing, appropriate use of personal protective equipment such as rubber gloves and/or cotton liners where indicated, use of barrier creams, use of moisturizers and raising awareness of the risks of OSD.[2] Personal protective equipment can vary in form, for example it can be gloves, aprons, overalls, hats, masks, safety boots etc.[10] Protective gloves contain substances that can act as sensitizers to the skin. The HSE has provided guidance on the selection of gloves.[12] Barrier creams are a topical preparation applied to the skin in order to provide a barrier.[2] They often contain lanolin, paraffin, silicones or polyethylene glycols.[10] Barrier creams are used to protect employees against work-related skin disease; however, occasionally the substances contained in these creams can themselves cause sensitization.[2,10] Moisturizers, or emollients, are used for regenerative skin care before, during and after work.[2]

Systematic Reviews

This section provides an overview of currently published systematic reviews on the incidence, prevalence, prevention and effectiveness of interventions (as described above) amongst wet workers. The terms 'incidence' and 'prevalence' are clearly defined in the field of epidemiology as: (i) prevalence: quantifying instances of a given disease, or other conditions, in a given population at a designated time, and (ii) incidence: quantifying new instances.[13]

One systematic review has been published on the prevention of OIHD amongst wet workers, and two other systematic reviews have addressed the management of skin disease in the workplace. Bauer et al[14] conducted a Cochrane review of Randomized Controlled Trials (RCTs) published between 2003 and 2011. Four international studies met the inclusion criteria. The overall review produced positive findings in respect of primary prevention of OIHD: the beneficial effects of using barrier creams and emollients, and an absence of harmful effects. None of the RCTs identified any problems with the efficacy of glove use. Due to the lack of statistical significance that emerged from the review, Bauer et

al[14] concluded that there is a need for larger studies to determine if primary prevention is effective and, if so, which is the best preventive measure. The main limitations of the review were the: (i) limited numbers of RCTs; (ii) methodological weaknesses of the studies identified for example short-term studies and the application of interventions restricted to healthy people; and (iii) complete absence of studies which support or refute the use of gloves as primary prevention. The fundamental forms of prevention that emerged from the review were the change of workers' behaviour by use of creams, reduction of hand washing as well as refraining from wet work.

Saary et al[15] conducted a systematic review of international studies published between 1960 and 2003 to provide the Workplace Safety and Insurance Board (WSIB) of Ontario, Canada with evidence-based recommendations regarding treatment decisions for OCD.[15] Forty-nine studies conducted in a range of countries met the inclusion criteria. Barrier creams containing dimethicone or perfluoropolyethers, cotton liners, and softened fabrics prevented irritant contact dermatitis (ICD). Lipid-rich moisturizers both prevented and treated irritant CD. Topical skin protectant and quaternium 18 bentonite (organoclay) prevented dermatitis. Diethylenetriamine pentaacetic acid (chelator) cream prevented nickel, chrome, and copper dermatitis. Potent or moderately potent steroids effectively treated allergic contact dermatitis (ACD). There were no macrolide immunomodulator trials that met inclusion criteria.[15] A limited number of interventions effectively prevented or treated OICD and OACD, but well-controlled, outcome-blinded studies, particularly in the area of ACD prevention were recommended.[15]

Smedley et al[16] performed a systematic review of 11 international RCT's on the management of occupational dermatitis focussing on HCWs. Whilst a number of conclusions were drawn, five in particular can be regarded as the most relevant to the proposed review. First, HCWs should seek early treatment for dermatitis. Second, in severe cases of acute dermatitis, work adjustments should be applied. Third, HCWs with dermatitis should follow a particular skin programme (for hand hygiene and hand care). Fourth, the need for further research on the risk of HCWs to transfer infection to patients is evident. Fifth, it remains unclear to what extent health surveillance is effective in reducing dermatitis. Two key limitations of the literature were identified by Smedley et al.[16] The first was non-statistical significance of the findings (large studies failed to determine whether primary prevention is helpful) and therefore, a comprehensive review that includes evidence from other quantitative study designs may be useful in synthesizing a broad range of evidence. The second was a lack of intervention uniformity. Although these limitations may still affect the proposed review, careful consideration will be given to inclusion/exclusion criteria and appropriate methods of data synthesis and reporting .

Despite a lack of robust evidence regarding the prevention of OIHD, provided by previous systematic reviews, useful guidance can be drawn by conducting a further systematic review as initial literature searching has identified studies[17,18] conducted since the publication date of these previous reviews that could be included in the synthesis. Due to the emergence of recent literature, and the specific nature of the previous systematic reviews conducted on this topic[14,15,16] there is a need to: (i) identify and appraise a broader range of literature, including recent intervention studies, focused on the prevention

of OIHD amongst wet workers , and (ii) focus on the strategy and effectiveness of measures to prevent OIHD amongst HCWs. The aim of this systematic review is therefore to identify findings from RCTs and other quantitative study designs that can contribute to the evidence of the effectiveness of interventions aimed at preventing OIHD.

Inclusion criteria

Types of participants

In keeping with previous systematic reviews in this area[14,15,16] participants will include any workers from healthcare (e.g. nurses, doctors and allied health professionals) and also different wet work occupations (e.g. hairdressers, florists, catering workers, metal workers) that are at similar risk of OIHD[11] due to, for example, frequent hand washing, skin contact with substances contained in soaps and/or hand gels and/or prolonged use of gloves. Primary prevention studies will be included where participants have no pre-existing skin conditions. Mixed population (pre-existing and no pre-existing skin conditions) studies will be included if the data for participants without pre-existing skin conditions can be extracted separately.

Types of intervention(s)

This quantitative systematic review will consider studies that measure the effectiveness of the following interventions in the primary prevention of OIHD in wet workers at the workplace and at home (before and after work):

- use of moisturizers, for example high and low lipid content moisturizers
- barrier creams, for example barrier creams which may contain substances such as liquid paraffin lotion, lanolin oil, silicone or hydrocarbon
- gloves (rubber and/or cotton) and
- education (e.g. seminars and training courses; face-to-face or online delivery).

Due the variability in regimens, any dosage/intensity of preventive intervention for any length of time will be considered for inclusion in this review including complex interventions that combine more than one of the above interventions.

Types of comparator

This review will include studies that compare one type of intervention to another. Studies that compare an intervention to a control group who do not receive any intervention will also be included.

Types of outcomes

Primary outcome measures will include:

OIHD incidence, defined as:

- The proportion of wet workers who have developed any signs or symptoms of OIHD incidence diagnosed by the investigator, a health professional or the participants themselves.

OIHD severity, defined as:

- Clinical evaluation (severity/improvement) of the signs or symptoms either by the investigator or the participant. Any widely accepted clinical assessment or self-report measure will be included, such as questionnaires and clinical examinations of hands,[21,22,23] telephone interviews and questionnaires based on the Nordic Occupational Skin Questionnaire (NOSQ-2002),[19] self-administered questionnaires.[24]
- Adverse outcomes (e.g. infections, severe irritation or allergy to products applied in the studies) assessed by the participants and/or clinicians and/or outcome assessors reported in the studies.

Secondary outcome measures will include:

- Product evaluation (proportion of participants satisfied with the products given in the study including cosmetic, preventive and therapeutic properties of the products). Any information which may be recorded in the studies that rates the quality of the products will be considered as means of measurement either from the participants, or the clinicians or other outcome assessors. Product evaluation recorded in studies will provide an insight into any changes to participants' symptoms and is therefore considered a means of measuring product effectiveness.[14]
- Change of occupation because of OIHD versus staying in the occupation that may have been recorded in the studies, where the reason for changing occupation has been clearly stated as OIHD.

Types of studies

This review will consider for inclusion any experimental study design including randomized controlled trials, non-randomized controlled trials, quasi-experimental, and before and after studies.

Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the articles. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in English will only be considered for inclusion in this review. Studies published between 2004 – 2016 will be considered for inclusion in this review.

This covers the period employed by Bauer et al[14] up to the present day as well as the period since the HSE guidance note on skin disease was last amended. The medical guidance note titled 'Medical aspects of occupational skin disease'[2] released from the UK HSE in 1998 which has been re-printed with amendments most recently in 2004 is the most pertinent guideline on skin disease in the UK. The HSE although being a UK enforcing agency is internationally recognized and collaborates closely with various European and international bodies regarding occupational health and safety.

The databases to be searched include:

COCHRANE CENTRAL

MEDLINE

CINAHL

AMED

EMBASE

The search for unpublished studies will include: Google Scholar, Open DOAR, and Robert Gordon University's thesis database 'OPEN AIR'.

Initial keywords to be used will be:

'Dermatitis' 'Occupational Health' 'Occupational Skin Disease' The search may result in literature on occupations not relevant to this review being identified. Initial screening will therefore identify which occupations are included in these studies and will only include those who would be considered wet workers (healthcare workers, florists, hairdressers and barbers, cooks, beauticians, and metal working machine operatives.

Assessment of methodological quality

Quantitative papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Studies will be included if reviewers agree that they meet seven out of the ten criteria (Appendix 1) or, in the event of one or more criteria being not applicable to the study design in question to an appropriately reduced score. However, failure to meet certain criteria will result in exclusion regardless of score (e.g. Questions 1 for RCTs and Questions 8,9,10 for all studies).

Data collection

Quantitative data will be extracted from papers included in the review by two independent reviewers using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of

significance to the review question and specific objectives. Authors of primary studies will be contacted where necessary to clarify any unclear data or provide missing data.

Data synthesis

Quantitative data will, where possible be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Appropriate subgroup analyses will be conducted, i.e. by intervention type, exposure type, and/or study type. Effect sizes expressed as odds ratios (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs and interventions included in this review. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

No potential conflicts of interest are identified.

Acknowledgements

The reviewers would like to acknowledge Robert Gordon University for providing an opportunity for Zoi Papadatou to undertake the JBI Comprehensive Systematic Review Training Programme.
The authors would like to thank Pamela Kirkpatrick for providing helpful comments on an earlier draft of this manuscript.

References

1. Brown T. Strategies for prevention of occupational contact dermatitis: Occup Med (Oxf). 2004;54(7):450-457.
2. Health and Safety Executive (HSE). Medical aspects of occupational skin disease. Guidance Note MS 24. 1998;1-8.
3. Health and Safety Executive (HSE). How does skin come into contact with chemicals? [internet]. [cited March 2016 16th].
Available from:
http://www.hse.gov.uk/skin/employ/exposure.htm
4. Matterne U, Diepgen TL, Weisshaar E. A longitudinal application of three health behaviour models in context of skin protection behaviour in individuals with occupational skin disease. Psychol Health.

2011;26(9):1188-1207.

5. Diepgen TL. Occupational skin disease data in Europe. Int ArchOccup Environ Health. 2003;76(5):331-338.

6. Carder M, McNamee R, Turner S, Hussey L, Money A, Agius R. Improving estimates of specialist-diagnosed, work-related respiratory and skin disease. Occup Med (Oxf). 2011;61(1):33-39.

7. Health and Safety Executive (HSE). Work-Related Skin Disease in Great Britain 2014. [internet]. [cited March 2016 16th].

Available from:

http://www.hse.gov.uk/Statistics/causdis/dermatitis/index.htm

8. World Health Organisation (WHO). WHO guidelines on hand hygiene in health care: first global patient safety challenge. Clean care is safer care. Geneva: WHO, 2009.

9. Cox RAF, Edwards, FC, Palmer K. Fitness for work. The medical aspects. USA: Oxford University Press; 2000. p. 453-462.

10. Palmer K, Brown I, Hobson J. Fitness for work. The medical aspects. Oxford: Oxford University Press; 2013.

11. De Craecker W, Roskams N, Op de Beek R. European Agency for Safety and Health at Work. Occupational skin diseases and dermal Exposure in the European Union (EU-25): policy and practice overview. European Risk Observatory Report. Belgium, 2008.

12. Health and Safety Executive (HSE). Choosing the right gloves to protect skin: a guide for employers. [internet]. [cited March 2016 16th].

Available from:

http://www.hse.gov.uk/skin/employ/gloves.htm

13. Silman AJ, MacFarlane GJ. Epidemiological Studies. A Practical Guide. Cambridge: Cambridge University Press; 2002. p. 13-19.

14. Bauer A, Schmitt J, Bennett C, Coenraads PJ, Elsner P, English J et al. Interventions for preventing occupational irritant hand dermatitis (Review). The Cochraine Library 2010. 2010; CD004414(6):1-38.

15. Saary J, Qureshi R, Palda V, DeKevon J, Pratt M, Skotnicki-Grant S et al. A systematic review of contact dermatitis treatment and prevention. J Am Acad Dermatol. 2005;53(5):845-845.

16. Smedley J, Williams S, Peel P, Pedersen K. Management of occupational dermatitis in healthcare workers: a systematic review. Occup Environ Med. 2012; 69(4):276-279.

17. Bauer A. Prevention in Food Workers. In: Rustemeyer T, Elsner P, Swen-Malte J, Maibach HI. editors. Kanerva's Occupational Dermatology. revised ed. Berlin Heidelberg: Springer; 2012. p. 1197-1203.

18. Skudlik C, Weisshaar E, Scheidt R, Elsner P, Wulfhorst B, Schönfeld M, et al. First results from the multicentre study rehabilitation of occupational skin diseases–optimization and quality assurance of inpatient management (ROQ). Contact Dermatitis. 2012;66(3):140-147.

19. Flyvholm MA, Mygind K, Sell L, Jensen A, Jepsen KF. A randomised controlled intervention study on prevention of work related skin problems among gut cleaners in swine slaughterhouses. Occup

Environ Med. 2005;62(9):642-649.

20. Kutting B Baumeister W, Weistenhofer A, Pfahlberg A, Uter W, Drexler H. Effectiveness of skin protection measures in prevention of occupational hand eczema: results of a prospective randomized controlled trial over a follow-up period of 1 year. Br J Dermatol. 2010;162(2):362-370.

21. Dulon M, Pohrt U, Skudlik C, Nienhaus A. Prevention of occupational skin disease: a workplace intervention study in geriatric nurses. Br J Dermatol. 2009;161(2):337-344.

22. Funke U, Fartasch M, Diepgen L. Incidence of work-related hand eczema during apprenticeship: first results of a prospective cohort study in the car industry. Contact Dermatitis. 2001;44(3):166-172.

23. Uter W, Pfahlberg A, Gefeller O, Schwanitz HJ. Prevalence and incidence of hand dermatitis in hairdressing apprentices: results of the POSH study. Int Arch Occup Environ Health.1998;71(7):487-492.

24. Lind ML, Albin M, Brisman J, Kronholm-Diab K, Lillienberg L, Mikoczy Z, et al. Incidence of hand eczema in female Swedish hairdressers. Occup Environ Med. 2007;64(3):191-195.

Appendix I: Appraisal instruments

MAStARI Appraisal instrument

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

Appendix II: Data extraction instruments

MAStARI data extraction instrument

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Method

RCT ☐ Quasi-RCT ☐ Longitudinal ☐

Retrospective ☐ Observational ☐ Other ☐

Participants

Setting _____

Population _____

Sample size

Group A _____ Group B _____

Interventions

Intervention A _____

_____

Intervention B _____

_____

Authors Conclusions:

_____

_____

_____

Reviewers Conclusions:

_____

_____

_____

Study results

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number