

Review Title

The effectiveness of cabbage leaf application (treatment) on breast engorgement in breastfeeding women

Centres conducting review

Alice Lee Centre for Nursing Studies, National University of Singapore: A Collaborating Centre of the Joanna Briggs Institute

Primary reviewer/contact

Name: Boh Boi Wong SRN,SCM, BHSC (BSC Nursing),MEdECE

Telephone: +65 67917506

Email: bbwong@tmc-sin.com.sg

Second reviewer/contact

Name: Dr Serena Koh RN BSc (Hons),Adv Dip(Midwifery) PhD

Telephone: +65 6325 9220

Email: serena_koh@moh.gov.sg

Third reviewer/ contact

Name: Dr Desley Gail HEGNEYRN, BA (Hons),DNE, ,FRCNA,PhD

Telephone: + 65 6776 7135

Email: Desley_Hegney@nuhs.edu.sg

Review Title

The effectiveness of chilled/cold cabbage leaf application on breast engorgement in breastfeeding women

Review Questions/Objectives

This systematic review aims to synthesize the best available evidence on the effectiveness of cabbage leaves on engorged breasts in breastfeeding women.

BACKGROUND

Breast engorgement is defined by the medical dictionary as congestion and distension with fluid.¹ The lactation literature defines it as a swollen breast, caused by the buildup of breast milk during breastfeeding, and is often referred to as swelling and distension of the breasts and can be a painful condition.^{2,3} This is a common physiological problem for lactating mothers that is caused by the sudden increase in the volume of the breast milk due to lymphatic and vascular congestion with interstitial oedema during the first two weeks of breastfeeding.⁴ The reason why engorgement occurs in the first two weeks postpartum is that the mother and her baby are adjusting to the process of demand and supply: i.e. if the milk production is increased too rapidly this may exceed the capacity of the breast alveoli to store it.

If the milk is not removed the distention can lead to capillary blood circulation occlusion and reduce the cellular activity.⁵ It has also been proposed that low breast milk supply may further lead to the baby becoming fretful.^{6,7} Breast engorgement may occur due to insufficient emptying of the breast milk from the mother due to poor transfer of breast milk and incorrect latching or positioning of the baby during the process of suckling.^{2,4} Methods of measuring breast engorgement include: measurements of chest circumference changes⁸ and thermography.⁹ Ferris and Riedel have also proposed the use of a pressure gauge to measure skin tension^{10,11} as a way of evaluating and measuring breast engorgement.

Previous comparative research studies suggest that breast engorgement occurs most commonly from day three to five postpartum, with some women presenting as late as day nine to ten;^{7,12,13} or even day fourteen.¹⁴ It has also been reported that multiple peaks of engorgement throughout the breastfeeding period are not uncommon.^{15,16}

Engorgement of the breasts is associated with severe pain, nipple tenderness, fissures of the nipple and infection which can all result in subsequent cessation of breastfeeding.¹⁷ Breast engorgement can be characterized by low grade fever and absence of systemic symptoms. The breasts feel warm to touch and appear shiny and it can be quite painful for some women when the breasts become hard. Throughout the world, breast engorgement is one of the main reasons why women stop breastfeeding,¹⁷⁻¹⁹ or suffer from a reduced /short duration of breastfeeding.

In March, 2001 The World Health Organization (WHO) recommended an optimal duration of exclusive breastfeeding of six months.^{20,21}

Many methods for the treatment of breast engorgement have been explored. These include cold cabbage compresses,^{22,23} cold gel pads,²⁴ hot compresses and warm showers, which are used to activate the milk ejection reflex.²⁵ Further treatment methods which have been postulated include the use of therapeutic ultrasound,^{25,26} breast binding,^{12,13} breast massage,²⁷ herbal remedies, manual/electrical pump, anti inflammatory medication (such as serrapeptase [Danzen]²⁵ which reduces swelling).^{25,28} In Taiwan a Randomized Controlled Trial used Gua-Sha (massage) therapy as a form of treatment.^{29,30}

One approach which has met with a high degree of success is the use of diuretics and restricting the intake of fluids. One study on the use of diuretics found that 85.7% of mothers displayed marked improvement after 3 days.^{22, 28, 31} Nonetheless, the use of diuretics is not recommended for the nursing mother as they reduce the production of breast milk due to the dehydration from the diuretics.² Additionally, many women are reluctant to take drugs when breastfeeding.³²

Although diuretics and other drugs have been shown to be effective in the treatment of breast engorgement, for the reasons described above (i.e. the mother wishes to nurse her child or is unwilling to use a drug-based remedy), women are turning to non-medical treatments for breast engorgement, such as warm or cold compresses, breast massage, or the use of cold cabbage leaves. These non-medical interventions are receiving increasing attention as viable treatment methods^{22, 30, 33, 34} as they are more easily available and generally easy to use, convenient and cheap as compared to medical interventions. For example, many women's preferred treatment for breast engorgement is chilled cabbage leaves as the effect is stronger and takes effect quickly²⁴. Thus, determining the efficacy of non-medical interventions for treatment of breast engorgement is becoming increasingly important.

One non-medical intervention, cabbage leaf treatment, has become increasingly popular as it is cheap, easily available and is a natural remedy which some studies have found to be effective^{22, 24} while others have not.^{22, 28, 34} For example:

- Cabbage leaves have been found to be effective in the treatment of engorgement due to the drawing action of cabbage leaves on human tissue.³⁵
- A Quasi – experimental study on the difference in effectiveness between cold and room temperature cabbage leaves, concluded that there was no difference in effectiveness if the leaves were chilled before use.²⁴
- In Australia, a comparative study using cabbage leaf extract was used for the treatment of breast engorgement. It was found that the cabbage leaf extract cream and a placebo cream were effective in relieving discomfort and the two groups showed no differences on all outcome measures.³⁴
- In a quasi–experimental study in India cold cabbage leaves, as well as alternate hot and cold compresses, were used in the treatment of breast engorgement. It was found that hot and cold compresses were more effective than cold cabbage leaves in relieving pain due to breast engorgement.²²
- A systematic review of various forms of treatment for breast engorgement (including acupuncture, cabbage leaves, drug treatment and cold packs) concluded that there is insufficient evidence from trials on any intervention to justify widespread implementation.²⁶
- In Singapore a comparative study was carried out on breast engorgement using drugs and other various methods, including cabbage leaf treatment and its effectiveness as compared to medical/drug-related treatment, finding that drug treatment was more effective than chilled cabbage leaves and other non-medical interventions.²⁸

Existing research evidence has revealed discrepancies in findings of the effectiveness of cabbage leaf treatment. Additionally, the effectiveness of cabbage leaf treatment on its own is unclear as in many studies cabbage leaf treatment is combined with other forms of treatment, thus casting doubt over the effectiveness of cabbage leaf alone as a viable form of treatment. This systematic review will focus on the effectiveness of cabbage leaf treatment on breast engorgement.

Inclusion Criteria

Types of participants

The review will consider breastfeeding women aged thirteen to fifty years of age of any parity regardless of previous breast engorgement problems and treatments. The women chosen include participants from different geographical locations. The participants are all breastfeeding women in the first two weeks postpartum, as the first two weeks postpartum is the most crucial period for nursing mothers to establish their lactation and when breast engorgement is most likely to occur.

We will exclude women with mastitis, plugged ducts, breast abscess and women who have ceased breast feeding.

Types of Intervention

The review will consider the use of cabbage leaves to relieve breast engorgement. It will only include papers that provide data on cabbage leaf treatment for breast engorgement. It will exclude cabbage leaf extract creams, as it appears that cabbage extract cream is different to cabbage leaves.

As there is no consistent method/system of treatment in relation to the use of cold cabbage leaves (including the number of leaves used [which vary from one to three pieces]) and the duration of treatment [which varies from ten minutes to two hours], all these interventions will be considered. Furthermore, as the various studies do not specify if a specific type of leaf, any type of cabbage leaf will be included.^{33, 36-38}

Types of Outcomes

This review will consider studies that include the following outcome measures:

Primary Outcome

The primary outcome of interest is the effectiveness of cabbage leaves on breast engorgement, defined as a reduction in engorgement, the severity of the distention and the level of hardness to touch.

It should be noted that the pattern of experience of engorgement is different for all mothers⁸ and can occur in any of three patterns:

- a single experience of firm, tender breasts followed by a resolution of symptoms;
- multiple peaks of engorgement followed by resolution;
- intense and painful engorgement lasting up to fourteen days; and minimal breast changes.

Secondary Outcome

Duration of Breastfeeding. For the purpose of this systematic review, breastfeeding duration is recommended for an optimal duration of exclusive breastfeeding of six months by the World Health Organization (WHO).^{20, 21}

Types of studies

The review will consider any randomised controlled trials (RCTs). In the absence of RCTs other research designs, such as non-randomised controlled trials, before and after studies, case control studies, cohort studies, descriptive studies such as case series/reports, will be considered for inclusion to enable the identification of the current best evidence for the effects of cabbage leaf on breast engorgement in breastfeeding women.

Papers which include narration, are opinion based or obtained from general experience, will not be included.

Search Strategy

The search strategy aims to find both published and unpublished studies from inception of the relevant database to 2010 in the English Language. A three-step search strategy will be utilised in each component of this review. An initial limited search of MEDLINE, CINAHL and SCOPUS will be undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe an article. 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.

The databases to be searched include:

Cinahl

Medline

Scopus

Embase

Web of Science

Science Direct

The search for unpublished studies will include:

Google Scholar

Mednar

Proquest

Initial keywords to be used will be:

Breast engorgement

Lactation disorder

Breast swelling

Engorged

Breast milk retention

Breastfeeding

Relief

Treatment

Therapy

Duration of breastfeeding

Cabbage leaves/leaf

Postpartum women

The search strategy is set out in further detail in Appendix I

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 standardised critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and

Review Instrument (JBI-MAStARI) (Appendix II). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data Collection

Quantitative data will be extracted from papers included in the review using the standardised data extraction tool from JBI-MAStARI (Appendix III). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data Synthesis

Quantitative papers will, where possible be pooled in statistical meta-analysis using the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). All results will be subject to double data entry. Odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed using the standard Chi-square. Where statistical pooling is not possible the findings will be presented in narrative form.

Conflict of Interest

There are no conflicts of interest.

References

1. Black's Medical Dictionary. *Ulster Med J.* 1938 Apr;7(2):160.
2. Lawrence R LR. *Breastfeeding: A Guide for the Medical Professions.* St Louis: Mosby; 2005.
3. Lawrence R, Lawrence RM. . *Breastfeeding: A Guide for the Medical Professions.* 6th ed. Mosby, editor. St Louis: Mosby; 2005.
4. Giugliani ER. [Common problems during lactation and their management]. *J Pediatr (Rio J).* 2004 Nov;80(5 Suppl):S147-54.
5. Walker M. Breastfeeding and Engorgement. *Breastfeeding Abstracts.* 2000;20(2):11-2.
6. Graef P, McGhee K, Rozycki J, Fescina-Jones D, Clark JA, Thompson J, et al. Postpartum concerns of breastfeeding mothers. *J Nurse Midwifery.* 1988 Mar-Apr;33(2):62-6.
7. Humenick SS, Hill PD, Anderson MA. Breast Engorgement: Patterns and Selected Outcomes. *Journal of Human Lactation.* 1994 June 1, 1994;10(2):87-93.
8. Newton ManN. Postpartum engorgement of the breast. *Am J Obstet Gynecol.* 1951;61: 664-67.
9. Menczer J, Eskin BA. Evaluation of postpartum breast engorgement by thermography. *Obstet Gynecol.* 1969 Feb;33(2):260-3.
10. Ferris CD. Instrumentation system for breast engorgement evaluation. *Biomed Sci Instrum.* 1990;26:227-9.
11. Riedel L. Breast engorgement: subjective and objective measurements and patterns of occurrence in primiparous mothers. 1991.
12. Swift K, Janke J. Breast binding... is it all that it's wrapped up to be? *J Obstet Gynecol Neonatal Nurs.* 2003 May-Jun;32(3):332-9.
13. Brooten DA, Brown LP, Hollingsworth AO, Tanis JL, Donlen J. A comparison of four treatments to prevent and control breast pain and engorgement in nonnursing mothers. *Nurs Res.* 1983 Jul-Aug;32(4):225-9.
14. Hill PD, Humenick SS. The occurrence of breast engorgement. *Journal of Human Lactation.* 1994;10(2):79-86.
15. Humenick SS, Hill PD, Anderson MA. Breast engorgement: patterns and selected outcomes. *J Hum Lact.* 1994 Jun;10(2):87-93.
16. Neifert MR. Clinical aspects of lactation. Promoting breastfeeding success. *Clin Perinatol.* 1999 Jun;26(2):281-306, v-vi.
17. Eiger MS, and Sally Olds. *The Complete Book of Breast-feeding.* New York: Bantam Books. 1999.
18. Lee WT, Lui SS, Chan V, Wong E, Lau J. A population-based survey on infant feeding practice (0-2 years) in Hong Kong: breastfeeding rate and patterns among 3,161 infants below 6 months old. *Asia Pac J Clin Nutr.* 2006;15(3):377-87.
19. Lee N. Observations based upon multiple telephone contacts with new breastfeeding mothers. *J Hum Lact.* 1997 Jun;13(2):147-50.
20. Organisation WH. Exclusive Breastfeeding.
21. Organisation WH. THE OPTIMAL DURATION OF EXCLUSIVE BREASTFEEDING: A SYSTEMATIC REVIEW. Available from: http://www.who.int/nutrition/topics/optimal_duration_of_exc_bfeeding_review_eng.pdf.

22. Arora S, Vatsa M, Dadhwal V. A Comparison of Cabbage Leaves vs. Hot and Cold Compresses in the Treatment of Breast Engorgement. *Indian J Community Med.* 2008 Jul;33(3):160-2.
23. Robson BA. Breast engorgement in breastfeeding mothers: CASE WESTERN RESERVE UNIVERSITY (HEALTH SCIENCES); 1990.
24. Roberts KL. A comparison of chilled cabbage leaves and chilled gelpaks in reducing breast engorgement. *Journal of Human Lactation.* 1995;11(1):17-20.
25. Snowden HM, Renfrew MJ, Woolridge MW. Treatments for breast engorgement during lactation. *Cochrane Database Syst Rev.* 2001(2):CD000046.
26. Mangesi L, Dowswell T. Treatments for breast engorgement during lactation. *Cochrane Database Syst Rev.* 2010;9:CD006946.
27. Snowden HM, Renfrew MJ, Woolridge MW. WITHDRAWN: Treatments for breast engorgement during lactation. *Cochrane Database Syst Rev.* 2001(2):CD000046.
28. Kee WH TS, Lee V, Salmon YM. The treatment of breast engorgement with Serrapeptase (Danzen): a randomised double-blind controlled trial. *Singapore medical journal.* 1989;30(1):48-54.
29. Berens P. ABM clinical protocol 20: Engorgement. *Breastfeeding Medicine.* 2009;4(2):111-3.
30. Chiu J, Gau M, Kuo S, Chang Y, Tu H. Effects of Gua-Sha therapy on breast engorgement: a randomized controlled trial. *Journal of Nursing Research (Taiwan Nurses Association).* 2010;18(1):1-10.
31. Kee WH, Tan SL, Lee V, Salmon YM. The treatment of breast engorgement with Serrapeptase (Danzen): a randomised double-blind controlled trial. *Singapore Med J.* 1989 Feb;30(1):48-54.
32. Diane S. Aschenbrenner SJV. *Drug Therapy in Nursing.* 3rd Edition ed: Wolters Kluwer Health. 2009.
33. Huston-Neill E. Advisor forum. Cabbage leaves for breast engorgement. *Clinical Advisor for Nurse Practitioners.* 2001;4(7/8):50-.
34. Roberts KL, Reiter M, Schuster D. Effects of cabbage leaf extract on breast engorgement. *J Hum Lact.* 1998 Sep;14(3):231-6.
35. Caplan LM. Drawing action of cabbage leaves. *Journal of Human Lactation.* 1999;15(1):7-8.
36. Roberts KL, Reiter M, Schuster D. Effects of cabbage leaf extract on breast engorgement. *Journal of Human Lactation.* 1998;14(3):231-6.
37. Arora S, Vatsa M, Dadhwal V. Cabbage leaves vs hot and cold compresses in the treatment of breast engorgement. *Nurs J India.* 2009 Mar;100(3):52-4.
38. Nikodem VC, Danziger D, Gebka N, Gulmezoglu AM, Hofmeyr GJ. Do cabbage leaves prevent breast engorgement? A randomized, controlled study. *Birth: Issues in Perinatal Care.* 1993;20(2):61-4.
39. Lee N. Observations Based Upon Multiple Telephone Contacts with New Breastfeeding Mothers. *Journal of Human Lactation.* 1997;13(2):147-50.
40. McLachlan Z, Milne EJ, Lumley J, Walker BL. Ultrasound treatment for breast engorgement: a randomised double blind trail. *Breastfeeding Review.* 1993;2(7):316-20.
41. Roberts KL, Reiter M, Schuster D. A comparison of chilled and room temperature cabbage leaves in treating breast engorgement. *Journal of Human Lactation.* 1995;11(3):191-4.

42. Shiao SH. Randomized controlled trial of kangaroo care with fullterm infants: effects on maternal anxiety, breastmilk maturation, breast engorgement, and breastfeeding status: Case Western Reserve University (Health Sciences); 1997.

Appendix 1 – Search Strategy

MEDLINE	
Search 1 - A AND B	
Search 2 - B AND C	
Search 3 – B AND D	
Search 4 – B AND C AND D	
Search 5 – B AND C AND E	
Area A – 1 OR 2	
1	Cabbage [MeSH]
2	Cabbage lea*
Area B – 3 OR 4 OR 5 OR 6 OR 7	
3	Breast engorgement [MeSH]
4	Lactation disorder [MeSH]
5	Engorged [Mesh]
6	Breast swelling
7	Breast milk retention
Area C – 8 OR 9 OR 10	
8	Treatment
9	Relief
10	Therapy
Area D – 11 OR 12	
11	Breastfeeding [Mesh]
12	Duration of Breastfeeding
Area E – 13	
13	Postpartum women

CINAHL	
Search 1 - A AND B	
Search 2 - B AND C	
Search 3 – B AND D	
Search 4 – B AND C AND D	
Search 5 – B AND C AND E	
Area A – 1 OR 2	
1	Cabbage [MeSH]
2	Cabbage lea*
Area B – 3 OR 4 OR 5 OR 6 OR 7	
3	Breast engorgement [MeSH]
4	Lactation disorder [MeSH]
5	Engorged [Mesh]
6	Breast swelling
7	Breast milk retention
Area C – 8 OR 9 OR 10	
8	Treatment
9	Relief

10	Therapy
Area D – 11 OR 12	
11	Breastfeeding [Mesh]
12	Duration of Breastfeeding
Area E – 13	
13	Postpartum women

SCOPUS	
Search 1 - A AND B	
Search 2 - B AND C	
Search 3 – B AND D	
Search 4 – B AND C AND D	
Search 5 – B AND C AND E	
Area A – 1 OR 2	
1	Cabbage [MeSH]
2	Cabbage lea*
Area B – 3 OR 4 OR 5 OR 6 OR 7	
3	Breast engorgement [MeSH]
4	Lactation disorder [MeSH]
5	Engorged [Mesh]
6	Breast swelling
7	Breast milk retention
Area C – 8 OR 9 OR 10	
8	Treatment
9	Relief
10	Therapy
Area D – 11 OR 12	
11	Breastfeeding [Mesh]
12	Duration of Breastfeeding
Area E – 13	
13	Postpartum women

EMBASE	
Keyword searches – key word searches were carried out	
1	Cabbage/exp AND leaf AND engorgement
2	Cabbage/exp AND leaves AND engorgement
3	Cabbage/exp AND leaves AND breast/exp engorgement
4	Cabbage/exp AND leaves AND lactation disorder
8	Breast/exp engorgement AND treatment
9	Breast/exp engorgement AND Relief
10	Breast/exp engorgement AND Therapy
11	Cabbage/exp AND leaf AND Breastfeeding
12	Cabbage/exp AND leaf AND Duration of Breastfeeding
13	Breast/exp engorgement AND Postpartum women

Web of Science	
Keyword searches – key word searches were carried out	
1	Cabbage AND leaf AND engorgement
2	Cabbage AND leaves AND engorgement
3	Cabbage AND leaves AND breast engorgement
4	Cabbage AND leaves AND lactation disorder
8	Breast engorgement AND treatment
9	Breast engorgement AND Relief
10	Breast engorgement AND Therapy
11	Cabbage AND leaf AND Breastfeeding
12	Cabbage AND leaf AND Duration of Breastfeeding
13	Breast engorgement AND Postpartum women

Science Direct	
Keyword searches – key word searches were carried out	
1	Cabbage AND leaf AND engorgement
2	Cabbage AND leaves AND engorgement
3	Cabbage AND leaves AND breast engorgement
4	Cabbage AND leaves AND lactation disorder
8	Breast engorgement AND treatment
9	Breast engorgement AND Relief
10	Breast engorgement AND Therapy
11	Cabbage AND leaf AND Breastfeeding
12	Cabbage AND leaf AND Duration of Breastfeeding
13	Breast engorgement AND Postpartum women

Google Scholar	
Keyword searches – the following key words were searched in Google Scholar	
1	Cabbage AND leaf AND engorgement
2	Cabbage AND leaves AND engorgement
3	Cabbage AND leaves AND breast engorgement
4	Cabbage AND leaves AND lactation disorder
8	Breast engorgement AND treatment
9	Breast engorgement AND Relief
10	Breast engorgement AND Therapy
11	Cabbage AND leaf AND Breastfeeding
12	Cabbage AND leaf AND Duration of Breastfeeding
13	Breast engorgement AND Postpartum women

Mednar

Keyword searches – the following key words were searched in Google Scholar

1	Cabbage AND leaf AND engorgement
2	Cabbage AND leaves AND engorgement
3	Cabbage AND leaves AND breast engorgement
4	Cabbage AND leaves AND lactation disorder
8	Breast engorgement AND treatment
9	Breast engorgement AND Relief
10	Breast engorgement AND Therapy
11	Cabbage AND leaf AND Breastfeeding
12	Cabbage AND leaf AND Duration of Breastfeeding
13	Breast engorgement AND Postpartum women

Proquest

Keyword searches – the following key words were searched in Google Scholar

1	Cabbage AND leaf AND engorgement
2	Cabbage AND leaves AND engorgement
3	Cabbage AND leaves AND breast engorgement
4	Cabbage AND leaves AND lactation disorder
8	Breast engorgement AND treatment
9	Breast engorgement AND Relief
10	Breast engorgement AND Therapy
11	Cabbage AND leaf AND Breastfeeding
12	Cabbage AND leaf AND Duration of Breastfeeding
13	Breast engorgement AND Postpartum women

Appendix II: Critical Appraisal tools

JBI Critical Appraisal Checklist for Experimental Studies

Reviewer _____ Date _____
Author _____ Year _____ Record Number _____

	Yes	No	Unclear
1. Was the assignment to treatment groups truly random?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were participants blinded to treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was allocation to treatment groups concealed from the allocator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were those assessing outcomes blind to the treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were the control and treatment groups comparable at entry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were groups treated identically other than for the named interventions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in the same way for all groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info.

Comments (Including reasons for exclusion) :

JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer _____ Date _____
Author _____ Year _____ Record Number _____

	Yes	No	Unclear
1. Is sample representative of patients in the population as a whole?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are the patients at a similar point in the course of their condition/illness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has bias been minimised in relation to selection of cases and of controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. Were outcomes measured in a reliable way?

9. Was appropriate statistical analysis used?

Overall appraisal: Include

Exclude

Seek further info.

Comments (Including reasons for exclusion):

JBI Critical Appraisal Checklist for Descriptive/ Case Series

Reviewer _____ Date _____
 Author _____ Year _____ Record Number _____

	Yes	No	Unclear
1. Was study based on a random or pseudorandom sample?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If comparisons are being made, was there sufficient descriptions of the groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 Overall appraisal: Include Exclude Seek further info.

Comments (Including reasons for exclusion):

Appendix III: Data Extraction Form (Quantitative Data)

Author _____ Record Number _____ Journal _____

Year _____ Reviewer _____

Method _____

Setting _____ Participants _____

Number of Participants

Group A

Group B

Interventions

Intervention A

Intervention B

Outcomes Measures

Outcome Description	Scale / Measure

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' conclusion

Reviewers' conclusion
