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TABLE OF CONTENTS

ABSTRACT	1
PLAIN LANGUAGE SUMMARY	3
SUMMARY OF FINDINGS	4
BACKGROUND	12
OBJECTIVES	13
METHODS	13
RESULTS	17
Figure 1.	18
Figure 2.	20
Figure 3.	21
DISCUSSION	28
AUTHORS' CONCLUSIONS	30
ACKNOWLEDGEMENTS	31
REFERENCES	32
CHARACTERISTICS OF STUDIES	35
DATA AND ANALYSES	66
Analysis 1.1. Comparison 1: Cabbage leaf treatments versus other treatments/placebo, Outcome 1: Breast pain (0-10 VAS; higher score = more pain)	68
Analysis 1.2. Comparison 1: Cabbage leaf treatments versus other treatments/placebo, Outcome 2: Breast hardness (higher score = more hardness)	68
Analysis 1.3. Comparison 1: Cabbage leaf treatments versus other treatments/placebo, Outcome 3: Breast engorgement (measured with 6-point engorgement scale)	69
Analysis 1.4. Comparison 1: Cabbage leaf treatments versus other treatments/placebo, Outcome 4: Maternal opinion of treatment: women satisfied or very satisfied	69
Analysis 1.5. Comparison 1: Cabbage leaf treatments versus other treatments/placebo, Outcome 5: Cessation of breastfeeding before six months	69
Analysis 2.1. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 1: Breast pain (higher score = more pain)	71
Analysis 2.2. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 2: Number of women with moderate or severe breast induration/hardness	71
Analysis 2.3. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 3: Breast engorgement (higher score = more pain)	72
Analysis 2.4. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 4: Cessation of breastfeeding	72
Analysis 2.5. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 5: Number of women with adverse effects	72
Analysis 3.1. Comparison 3: Medical treatment versus placebo, Outcome 1: Breast swelling (no improvement)	73
Analysis 3.2. Comparison 3: Medical treatment versus placebo, Outcome 2: Breast engorgement (symptoms not subsided after three days of treatment)	74
Analysis 3.3. Comparison 3: Medical treatment versus placebo, Outcome 3: Breast pain (no improvement)	74
Analysis 4.1. Comparison 4: Cold gel packs versus routine care, Outcome 1: Breast pain (higher score = more pain)	75
Analysis 4.2. Comparison 4: Cold gel packs versus routine care, Outcome 2: Breast hardness (higher score = more hardness) ...	75
Analysis 4.3. Comparison 4: Cold gel packs versus routine care, Outcome 3: Maternal opinion of treatment: women satisfied or very satisfied	75
Analysis 4.4. Comparison 4: Cold gel packs versus routine care, Outcome 4: Cessation of breastfeeding before six months	76
Analysis 5.1. Comparison 5: Massage-based therapies versus other treatments/routine care, Outcome 1: Breast pain (higher score = more pain)	76
Analysis 5.2. Comparison 5: Massage-based therapies versus other treatments/routine care, Outcome 2: Number of women with moderate or severe breast induration/hardness	76
Analysis 5.3. Comparison 5: Massage-based therapies versus other treatments/routine care, Outcome 3: Cessation of breastfeeding	77
Analysis 6.1. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 1: Breast pain (0-10 VAS; higher score = more pain)	78

Analysis 6.2. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 2: Breast engorgement (0-10 VAS; higher score = more pain)	78
Analysis 6.3. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 3: Breast engorgement ..	78
Analysis 6.4. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 4: Cessation of breastfeeding within 6 weeks	79
Analysis 6.5. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 5: Pyrexia	79
Analysis 6.6. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 6: Breast abscess	80
Analysis 7.1. Comparison 7: Ultrasound versus sham ultrasound, Outcome 1: Analgesic requirement	80
APPENDICES	80
WHAT'S NEW	81
HISTORY	81
CONTRIBUTIONS OF AUTHORS	81
DECLARATIONS OF INTEREST	81
SOURCES OF SUPPORT	81
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	82
NOTES	82
INDEX TERMS	82

[Intervention Review]

Treatments for breast engorgement during lactation

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ABSTRACT

Background

Engorgement is the overfilling of breasts with milk, often occurring in the early days postpartum. It results in swollen, hard, painful breasts and may lead to premature cessation of breastfeeding, decreased milk production, cracked nipples and mastitis. Various treatments have been studied but little consistent evidence has been found on effective interventions.

Objectives

To determine the effectiveness and safety of different treatments for engorgement in breastfeeding women.

Search methods

On 2 October 2019, we searched Cochrane Pregnancy and Childbirth's Trials Register, [ClinicalTrials.gov](https://clinicaltrials.gov), the WHO International Clinical Trials Registry Platform (ICTRP), and reference lists of retrieved studies.

Selection criteria

All types of randomised controlled trials and all forms of treatment for breast engorgement were eligible.

Data collection and analysis

Two review authors independently assessed trials for eligibility, extracted data, conducted 'Risk of bias' assessment and assessed the certainty of evidence using GRADE.

Main results

For this update, we included 21 studies (2170 women randomised) conducted in a variety of settings. Six studies used individual breasts as the unit of analysis.

Trials examined a range of interventions: cabbage leaves, various herbal compresses (ginger, cactus and aloe, hollyhock), massage (manual, electromechanical, Oketani), acupuncture, ultrasound, acupressure, scraping therapy, cold packs, and medical treatments (serrapeptase, protease, oxytocin). Due to heterogeneity, meta-analysis was not possible and data were reported from single trials. Certainty of evidence was downgraded for limitations in study design, imprecision and for inconsistency of effects. We report here findings from key comparisons.

Cabbage leaf treatments compared to control

For breast pain, cold cabbage leaves may be more effective than routine care (mean difference (MD) -1.03 points on 0-10 visual analogue scale (VAS), 95% confidence intervals (CI) -1.53 to -0.53; 152 women; very low-certainty evidence) or cold gel packs (-0.63 VAS points, 95%

CI -1.09 to -0.17; 152 women; very low-certainty evidence), although the evidence is very uncertain. We are uncertain about cold cabbage leaves compared to room temperature cabbage leaves, room temperature cabbage leaves compared to hot water bag, and cabbage leaf extract cream compared to placebo cream because the CIs were wide and included no effect.

For breast hardness, cold cabbage leaves may be more effective than routine care (MD -0.58 VAS points, 95% CI -0.82 to -0.34; 152 women; low-certainty evidence). We are uncertain about cold cabbage leaves compared to cold gel packs because the CIs were wide and included no effect.

For breast engorgement, room temperature cabbage leaves may be more effective than a hot water bag (MD -1.16 points on 1-6 scale, 95% CI -1.36 to -0.96; 63 women; very low-certainty evidence). We are uncertain about cabbage leaf extract cream compared to placebo cream because the CIs were wide and included no effect.

More women were satisfied with cold cabbage leaves than with routine care (risk ratio (RR) 1.42, 95% CI 1.22 to 1.64; 152 women; low certainty), or with cold gel packs (RR 1.23, 95% CI 1.10 to 1.38; 152 women; low-certainty evidence).

We are uncertain if women breastfeed longer following treatment with cold cabbage leaves than routine care because CIs were wide and included no effect.

Breast swelling and adverse events were not reported.

Compress treatments compared to control

For breast pain, herbal compress may be more effective than hot compress (MD -1.80 VAS points, 95% CI -2.07 to -1.53; 500 women; low-certainty evidence). Massage therapy plus cactus and aloe compress may be more effective than massage therapy alone (MD -1.27 VAS points, 95% CI -1.75 to -0.79; 100 women; low-certainty evidence). In a comparison of cactus and aloe compress to massage therapy, the CIs were wide and included no effect.

For breast hardness, cactus and aloe cold compress may be more effective than massage (RR 0.66, 95% CI 0.51 to 0.87; 102 women; low-certainty evidence). Massage plus cactus and aloe cold compress may reduce the risk of breast hardness compared to massage alone (RR 0.38, 95% CI 0.25 to 0.58; 100 women; low-certainty evidence).

We are uncertain about the effects of compress treatments on breast engorgement and cessation of breastfeeding because the certainty of evidence was very low.

Among women receiving herbal compress treatment, 2/250 experienced skin irritation compared to 0/250 in the hot compress group (moderate-certainty evidence).

Breast swelling and women's opinion of treatment were not reported.

Medical treatments compared to placebo

Protease may reduce breast pain (RR 0.17, 95% CI 0.04, 0.74; low-certainty evidence; 59 women) and breast swelling (RR 0.34, 95% CI 0.15 to 0.79; 59 women; low-certainty evidence), whereas serrapeptase may reduce the risk of engorgement compared to placebo (RR 0.36, 95% CI 0.14 to 0.88; 59 women; low-certainty evidence).

We are uncertain if serrapeptase reduces breast pain or swelling, or if oxytocin reduces breast engorgement compared to placebo, because the CIs were wide and included no effect.

No women experienced adverse events in any of the groups receiving serrapeptase, protease or placebo (low-certainty evidence).

Breast induration/hardness, women's opinion of treatment and breastfeeding cessation were not reported.

Cold gel packs compared to control

For breast pain, we are uncertain about the effectiveness of cold gel packs compared to control treatments because the certainty of evidence was very low.

For breast hardness, cold gel packs may be more effective than routine care (MD -0.34 points on 1-6 scale, 95% CI -0.60 to -0.08; 151 women; low-certainty evidence). It is uncertain if women breastfeed longer following cold gel pack treatment compared to routine care because the CIs were wide and included no effect.

There may be little difference in women's satisfaction with cold gel packs compared to routine care (RR 1.17, 95% CI 0.97 to 1.40; 151 women; low-certainty evidence).

Breast swelling, engorgement and adverse events were not reported.

Authors' conclusions

Although some interventions may be promising for the treatment of breast engorgement, such as cabbage leaves, cold gel packs, herbal compresses, and massage, the certainty of evidence is low and we cannot draw robust conclusions about their true effects. Future trials should aim to include larger sample sizes, using women - not individual breasts - as units of analysis.

PLAIN LANGUAGE SUMMARY

Treatment for breast engorgement (overfull, hard, painful breasts) in breastfeeding women

What is the issue?

Breast engorgement is the overfilling of breasts with milk, leading to swollen, hard, painful breasts. Engorgement is more common when feeding is scheduled, when women have difficulty breastfeeding or are separated from their babies. This leads to breasts not being emptied sufficiently.

Why is this important?

Breast engorgement is distressing and leads to complications such as inflammation of the breast, sore/cracked nipples and reduced milk supply. Consequently, women may stop breastfeeding. Consistent evidence on effective forms of treatment is lacking.

What evidence did we find?

For this update, we searched for trials (on 2 October 2019) exploring any treatments for breast engorgement in breastfeeding women. We found 21 studies involving 2170 women and 17 different interventions.

For breast pain, cold cabbage leaves may be better than routine care or cold gel packs. We are uncertain whether cold cabbage leaves are better than room temperature cabbage leaves, or room temperature cabbage leaves than hot water bag, or cabbage leaf extract cream than placebo cream because the certainty of evidence was low. For breast hardness, cold cabbage leaves may be better than routine care but we are uncertain if they are better than cold gel packs. For breast engorgement, room temperature cabbage leaves may be better than a hot water bag. We are uncertain if cabbage leaf extract cream is better than placebo cream because the certainty of evidence was low.

For breast pain, herbal compress may be better than hot compress and massage therapy plus cactus/aloe compress may be better than massage therapy alone. We are uncertain if cactus/aloe compress is better than massage therapy because the certainty of evidence was low. Cactus/aloe compress may be better for breast hardness compared to massage therapy. Massage plus cactus/aloe cold compress may be better for breast hardness compared to massage alone. We are uncertain about the effects of compress treatments on breast engorgement and stopping breastfeeding because the certainty of evidence was very low.

Protease may be better for breast pain and breast swelling, whereas serrapeptase may be better for engorgement compared to placebo. We are uncertain if serrapeptase reduces breast pain or swelling, or if oxytocin reduces breast engorgement compared to placebo, because the certainty of evidence was low.

For breast pain, we are uncertain about the effectiveness of cold gel packs compared to control treatments because the certainty of evidence was low. For breast hardness, cold gel packs may be better than routine care. We are uncertain if more women stop breastfeeding following cold gel pack treatment compared to routine care because the certainty of evidence was low.

In terms of women's opinion of treatment, the certainty of evidence was low. More women were satisfied with cold cabbage leaves than with routine care, or with cold gel packs. There may be little difference in women's satisfaction between cold gel packs and routine care.

Three studies reported adverse events. No women experienced adverse events in any of the groups receiving medication (low-certainty evidence) and 2/250 women receiving herbal compress treatment experienced skin irritation compared to 0/250 in the hot compress group (moderate-certainty evidence).

What does this mean?

There is some evidence to suggest that some treatments may be promising for the treatment of breast engorgement, such as cabbage leaves, cold gel packs, herbal compresses and massage, but more studies are needed for the true effect of these interventions to be known.

SUMMARY OF FINDINGS

Summary of findings 1. Cabbage leaf treatments versus other treatments/placebo for breast engorgement during lactation

Cabbage leaf treatments versus other treatments/placebo for breast engorgement during lactation

Patient or population: women with breast engorgement during lactation

Setting: obstetric outpatient clinic

Intervention: cabbage leaf treatments

Comparison: control treatments

Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Breast pain assessed with: 0-10 visual analogue scale (higher score = greater pain), follow-up: range from 2 hours to 36 hours	One study found cold cabbage leaves to be more effective than routine care (MD -1.03, 95% CI -1.53 to -0.53; 1 study; 152 women) or cold gel packs (-0.63, 95% CI -1.09 to -0.17; 1 study; 151 women). Another study found cold cabbage leaves to be slightly more effective than room temperature cabbage leaves but the data were reported in a way that was unsuitable for analysis (1 study, 28 women). One study found room temperature cabbage leaves to be slightly more effective than hot water bag but with wide confidence intervals that included no effect (MD -0.16, 95% CI -0.39 to 0.07; 1 study; 63 women). One study found cabbage leaf extract cream to be slightly less effective than placebo cream but with wide confidence intervals that included no effect (MD 0.40, 95% CI -0.67 to 1.47; 1 study; 39 women).	393 (4 RCTs) data not pooled	⊕⊕⊕⊕ VERY LOW ^{1 2 3}
Breast induration/hardness assessed with: 1-6 breast engorgement assessment scale (higher score = greater hardness), follow-up: 4 hours	One study found cold cabbage leaves to be more effective than routine care (MD -0.58, 95% CI -0.82 to -0.34; 1 study 152 women). The same study found cold cabbage leaves to be slightly more effective than cold gel packs but with wide confidence intervals that included no effect (MD -0.24, 95% CI -0.48 to -0.00; 1 study; 151 women).	227 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 3}
Breast swelling	Not reported		
Breast engorgement assessed with: 1-6 breast engorgement assessment scale (higher score = greater engorgement), follow-up: range from 2 hours to 36 hours	One study found room temperature cabbage leaves to be more effective than hot water bag (MD -1.16, 95% CI -1.36 to -0.96; 1 study; 63 women). One study found cabbage leaf extract cream to be slightly less effective than placebo cream but with wide confidence intervals that included no effect (MD 0.20, 95% CI -0.18 to 0.58; 1 study; 39 women).	102 (2 RCTs) data not pooled	⊕⊕⊕⊕ VERY LOW ^{1 2 3}

Maternal opinion of treatment follow-up: 4 hours	In one study, 29% more women were satisfied or very satisfied with cold cabbage leaves than with routine care (RR 1.42, 95% CI 1.22 to 1.63; 152 women). In the same study, 19% more women were satisfied or very satisfied with cold cabbage leaves than with cold gel packs (RR 1.23, 95% CI 1.10 to 1.38; 152 women).	228 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 3}
Cessation of breastfeeding follow-up: 6 months	In one study, slightly more women in the cold cabbage leaf group stopped breastfeeding within 6 months than in the routine care group (RR 1.75, 95% CI 0.93 to 3.30; 108 women) or the cold gel pack group (RR 1.70, 95% CI 0.92 to 3.13; 111 women) but the confidence intervals were wide and included no effect.	111 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 3}
Number of women with adverse events	Not reported		

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to risk of detection bias and performance bias in most studies

² Downgraded one level for inconsistency due to large variation in the extent to which the intervention had an effect

³ Downgraded one level for imprecision due to small number of participants

Summary of findings 2. Compress treatments versus other treatments/routine care for breast engorgement during lactation

Compress treatments versus other treatments/routine care for breast engorgement during lactation

Patient or population: women with breast engorgement during lactation

Setting: obstetric outpatient clinic

Intervention: compress treatments

Comparison: control treatments

Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Breast pain assessed with: 0-10 visual analogue scale (higher score = greater pain), follow-up: range from 20 minutes to 7 days	One study found herbal compress to be more effective than hot compress (MD -1.80, 95% CI -2.07 to -1.53; participants = 500; studies = 1). Another study found cactus and aloe compress to be slightly less effective than massage therapy but with wide confidence intervals that included no effect (MD 0.17, 95% CI -0.55 to 0.89; participants = 102; studies = 1). One study found massage therapy plus cactus and aloe com-	602 (2 RCTs) data not pooled	⊕⊕⊕⊕ LOW ¹

	press to be more effective than massage therapy alone (MD -1.27, 95% CI -1.75 to -0.79; participants = 100; studies = 1).		
Breast induration/hardness assessed with: presence of moderate or severe breast induration, follow-up: 7 days	One study found 28.6% fewer women had breast hardness with cactus and aloe cold compress compared to massage therapy (RR 0.66, 95% CI 0.51 to 0.87; participants = 102; studies = 1). The same study found 52.1% fewer women had breast hardness with massage plus cactus and aloe compress alone compared to massage alone (RR 0.38, 95% CI 0.25 to 0.58; participants = 100; studies = 1).	152 (1 RCT)	⊕⊕⊕⊕ LOW ¹
Breast swelling	Not reported		
Breast engorgement assessed with: 0-19 breast engorgement assessment scale (higher score = greater pain), follow-up: range from 2 days to 7 days	One study found herbal compress with hollyhock leaf to be more effective than warm compress (MD -2.82, 95% CI -4.60 to -1.04; participants = 40; studies = 1). One study found lower engorgement scores in the ginger compress group compared to the routine care group but since the data were reported according to left and right breast it is unclear what the true effect is.	116 (2 RCTs) data not pooled	⊕⊕⊕⊕ VERY LOW ^{1 2 3}
Maternal opinion of treatment	Not reported		
Cessation of breastfeeding, follow-up: 7 days	In one study, 9/52 women in the cactus and aloe cold compress group stopped breastfeeding compared to 8/50 women in the massage group. In the same study, 2/50 women in the cactus and aloe cold compress plus massage therapy group stopped breastfeeding compared to 8/50 women in the massage group.	102 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{1 3}
Number of women with adverse events, follow-up: 24 hours	One study found more women in the herbal compress group had adverse events (skin irritation) compared to the hot compress group (2/250 and 0/250, respectively) (RR 5.00, 95% CI 0.24 to 103.62; 1 study; 500 women)	500 (1 RCT)	⊕⊕⊕⊕ MODERATE ⁴

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded two levels due to risk of selection, detection and performance bias

² Downgraded one level due to indirectness: some data reported per breast

³ Downgraded one level for imprecision due to small number of participants

⁴ Downgraded one level for imprecision: few events and wide confidence interval including no effect

Summary of findings 3. Medical treatments versus placebo for breast engorgement

Medical treatments versus placebo for breast engorgement

Patient or population: women with breast engorgement

Setting: obstetric outpatient clinic

Intervention: medical treatments (oxytocin, serrapeptase or protease)

Comparison: placebo

Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Breast pain assessed with: presence of moderate or severe pain, follow-up: range from 3 to 4 days	One study found 27.7% fewer women experienced breast pain with protease than with placebo (RR 0.17, 95% CI 0.04 to 0.74; participants = 59; studies = 1). Another study found fewer women experienced breast pain with serrapeptase than with placebo but with wide confidence intervals that included no effect (RR 0.56, 95% CI 0.21 to 1.49; participants = 70; studies = 1).	70 (2 RCTs) data not pooled	⊕⊕⊕⊕ LOW ^{1 2}
Breast induration/hardness	Not reported		
Breast swelling assessed with: no improvement in breast swelling, follow-up: 4 days	In one study, 33.0% fewer women had breast swelling with protease compared to placebo (RR 0.34, 95% CI 0.15 to 0.79; participants = 59; studies = 1) and one study found a slightly lower risk with serrapeptase compared to placebo but with wide confidence intervals that included no effect (RR 0.75, 95% CI 0.36 to 1.55; participants = 70; studies = 1).	129 (2 RCTs) data not pooled	⊕⊕⊕⊕ LOW ^{1 2}
Breast engorgement, follow-up: range from 3 to 7 days	In one study, 25.6% fewer women had breast engorgement with serrapeptase than with placebo (RR 0.36, 95% CI 0.14 to 0.88; participants = 70; studies = 1). One study found a greater risk of symptoms persisting after 3 days of treatment with oxytocin than with placebo but with wide confidence intervals that included no effect (RR 3.13, 95% CI 0.68 to 14.44; participants = 45; studies = 1).	115 (2 RCTs) data not pooled	⊕⊕⊕⊕ LOW ^{1 2}
Maternal opinion of treatment	Not reported		
Cessation of breast-feeding	Not reported		
Number of women with adverse events, follow-up: range from 3 to 4 days	In one study, there were no adverse events in either the serrapeptase group or the placebo group. In another study, there were no adverse events in either the protease group or the placebo group.	129 (2 RCTs) data not pooled	⊕⊕⊕⊕ LOW ^{1 2 3}

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to serious risk of allocation bias

² Downgraded one level due to serious imprecision: very few events

³ Downgraded two levels due to risk of allocation bias and bias arising from industry funding

Summary of findings 4. Cold gel packs versus routine care for breast engorgement during lactation

Cold gel packs versus routine care for breast engorgement during lactation

Patient or population: women with breast engorgement during lactation

Setting: obstetric outpatient clinic

Intervention: cold gel packs

Comparison: routine care

Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Breast pain assessed with: 0-10 visual analogue scale (higher score = more pain), follow-up: range from 2 hours to 8 hours	One study found slightly lower pain scores in the cold gel pack group than in the routine care group but with wide confidence intervals that included no effect (MD -0.40, 95% CI -0.91, 0.11; 1 study; 151 women). One study found slightly lower pain scores in the cold gel pack group than in the cold cabbage leaf group but since data were reported per breast it is unclear what the true effect is. One study found lower pain scores in the cold pack group than in the control group but the data were not reported in full.	200 (3 RCTs) data not pooled	⊕⊕⊕⊕ VERY LOW ^{1 2}
Breast induration/hardness assessed with: 1-6 breast engorgement assessment scale (higher score = greater hardness), follow-up: 4 hours	One study found cold gel packs to be more effective than routine care (MD -0.34, 95% CI -0.60 to -0.08; 1 study; 151 women).	151 (1 RCT)	⊕⊕⊕⊕ LOW ^{3 4}
Breast swelling	Not reported		
Breast engorgement	Not reported		
Maternal opinion of treatment, follow-up: range from 2 to 4 hours	In one study, slightly more women in the cold gel pack group were satisfied or very satisfied than in the routine care group but the confidence intervals were wide and included no effect (RR 1.17, 95% CI 0.97 to 1.40; 1 study; 151 women).	151 (1 RCT)	⊕⊕⊕⊕ LOW ^{3 4}

	Another study found two-thirds of 34 women preferred cold cabbage leaves to cold gel packs.		
Cessation of breast-feeding, follow-up: 6 months	In one study, slightly more women in the cold gel pack group stopped breastfeeding than in the routine care group but the confidence intervals were wide and included no effect (RR 1.03, 95% CI 0.50 to 2.14; 1 study, 109 women).	109 (1 RCT)	⊕⊕⊕⊕ LOW ^{3 4}
Number of women with adverse events	Not reported		

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded two levels due to risk of bias: unclear randomisation procedures, risk of detection and performance bias

² Downgraded one level due to indirectness: some data reported per breast

³ Downgraded one level due to risk of detection bias and performance bias

⁴ Downgraded one level for imprecision due to small number of participants

Summary of findings 5. Massage-based therapies versus other treatments/routine care for women with breast engorgement during lactation

Massage-based therapies versus other treatments/routine care for women with breast engorgement during lactation

Patient or population: women with breast engorgement during lactation

Setting: obstetric clinic

Intervention: massage-based therapies

Comparison: control treatments

Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Breast pain assessed with: 0-10 visual analogue scale (higher score = greater pain), follow-up: 7 days	One study found massage plus cactus and aloe cold compress was more effective than cactus and aloe cold compress alone (MD -1.44, 95% CI -2.14 to -0.74; 1 study; 102 women).	102 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}
Breast induration/hardness assessed with: presence of moderate or severe breast induration, follow-up: 7 days	One study found 24% fewer women had breast induration with massage plus cactus and aloe cold compress compared to cactus and aloe cold compress alone (RR 0.57, 95% CI 0.36 to 0.92; 1 study; 102 women).	102 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}

Breast swelling	Not reported		
Breast engorgement assessed with: 0-19 breast engorgement assessment scale or 0-10 visual analogue scale (higher score = greater pain), follow-up: 2 days	One study found lower breast engorgement scores in women who had Oketani massage than those who had routine care but the data were reported per breast so the true effect is unclear.	100 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 3}
Maternal opinion of treatment	Not reported		
Cessation of breastfeeding, follow-up: 7 days	In one study, slightly fewer women in the massage plus cactus and aloe cold compress group stopped breastfeeding than in the cactus and aloe cold compress only group but the confidence intervals were wide and included no effect (RR 0.23, 95% CI 0.05 to 1.02; 1 study; 152 women).	152 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}
Number of women with adverse events	Not reported		

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to risk of selection, detection and performance bias

² Downgraded one level for imprecision due to small number of participants

³ Downgraded one level due to indirectness: data reported per breast instead of per woman

Summary of findings 6. Other treatments versus other treatments/advice/routine care for women with breast engorgement during lactation

Other treatments versus other treatments/advice/routine care for women with breast engorgement during lactation

Patient or population: women with breast engorgement during lactation

Setting: obstetric outpatient clinic

Intervention: other therapies

Comparison: control treatments

Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Breast pain assessed with: 0-10 visual analogue scale (higher score = greater pain),	One study found Gua-Sha therapy was more effective than hot packs with massage (MD -2.01, 95% CI -2.60 to -1.42; 1 study; 54 women).	54 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}

Treatments for breast engorgement during lactation (Review)

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follow-up: 30 minutes			
Breast induration/hardness	Not reported		
Breast swelling	Not reported		
Breast engorgement assessed with: 0-19 breast engorgement assessment scale or 0-10 visual analogue scale (higher score = greater pain), follow-up: range from 30 minutes to 6 weeks	One study found Gua-Sha therapy was more effective than hot packs with massage (MD -2.42, 95% CI -2.98 to -1.86; 1 study; 54 women). One study found fewer women had breast engorgement symptoms with acupuncture than with usual care but the confidence intervals were wide and included no effect (RR 0.72, 95% CI 0.47 to 1.10; 1 study; 210 women). One study found lower breast engorgement scores in women who had acupressure than those who had routine care but the data were reported per breast so the true effect is unclear.	328 (3 RCTs) data not pooled	⊕⊕⊕⊕ VERY LOW ^{1 3 4}
Maternal opinion of treatment	Not reported		
Cessation of breastfeeding, follow-up: 6 weeks	In one study, slightly fewer women stopped breastfeeding in the acupuncture group than in the usual care group but the confidence intervals were wide and included no effect (RR 0.72, 95% CI 0.17 to 1.49; 1 study; 210 women).	210 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 5}
Number of women with adverse events	Not reported		

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to risk of selection and performance bias

² Downgraded one level for imprecision due to small number of participants

³ Downgraded one level for inconsistency: heterogeneity in effect size

⁴ Downgraded one level due to indirectness: some data reported per breast instead of per woman

⁵ Downgraded one level due to imprecision: wide 95% confidence interval consistent with both appreciable harm and benefit

BACKGROUND

In recognition of the importance of breastfeeding for maternal and infant well-being, and for society at large, the World Health Organization recommends that all babies should be exclusively breastfed for the first six months of life and then continue to receive breast milk, along with appropriate complementary foods, up to two years of age or beyond (WHO 2003). Despite this, fewer than 3% of women breastfeed their infants for 24 months (Carletti 2011; Hure 2013; Liu 2013). One of the most common factors associated with premature cessation of breastfeeding is difficulty with lactation (Odom 2013), including breast engorgement (Hauck 2011).

Description of the condition

Breast engorgement is the pathological overfilling of the breasts with milk, characterised by hard, painful, tight breasts and difficulty breastfeeding. It is usually due to compromised milk removal, either from separation of mother and newborn, restrictive feeding practices and/or ineffective sucking, or less commonly overproduction of milk. Augmentation mammoplasty (surgical enlargement of breasts) may also predispose to engorgement (Acarturk 2005). Engorgement should be differentiated from normal breast fullness, sometimes referred to as physiological breast engorgement (Nikodem 1993; Sankanagoudar 2011), occurring between day two to three postpartum, in which secretory activation of the breast (lactogenesis II) is triggered by the delivery of the placenta (progesterone withdrawal) and subsequent rise in prolactin levels (Hale 2007). This results in increased milk production and interstitial tissue oedema producing visibly larger, warmer and slightly uncomfortable breasts. In women with normal breast fullness, milk flow from the breasts is not hindered and with responsive, efficient breastfeeding, discomfort resolves within a few days.

Non-physiological breast engorgement, on the other hand, is a distressing and debilitating condition affecting between 15% and 50% of women (Hill 1994). Prevalence may be even higher, depending on the definition used. Where engorgement was described as part of an inflammatory process (any mixture of redness, pain, fever, breast tension and resistance in breast tissue), 75% of women in a Swedish study experienced symptoms within eight weeks postpartum (Kvist 2004). Some level of breast tenderness during the first five days after birth was experienced by 72% of women in a study by Hill and Humenick. Engorgement symptoms occur most commonly between the second and fifth days postpartum (Hill 1994; Roberts 1995b), peaking at day five (Hill 1994), but may occur as late as day 14 (Humenick 1994), and are usually diffuse, bilateral and may be associated with a low-grade fever. Complications are common and include sore/damaged nipples, mastitis, abscess formation, decreased milk supply (Giugliani 2004), premature introduction of breast milk substitutes, and premature cessation of breastfeeding (Mass 2004). Engorgement may inhibit women's perceived or actual ability to breastfeed. Difficulty in feeding the baby occurs in up to 82% of mothers with breast engorgement (Roberts 1995b), leading to worsening milk stasis. Given the importance of breastfeeding, and the significant discomfort experienced by women with engorgement, effective remedies need to be determined.

Description of the intervention

Many interventions for the treatment of breast engorgement have been suggested in the past. Some treatments have been abandoned, such as mechanical compression (binding) of the breasts, complete (often forceful) manual emptying of the breasts, fluid restriction, and the use of diuretics, oestrogens and bromocriptine, due to safety concerns. These treatments are no longer recommended. Others, such as some anti-inflammatory medications (bromelain, serrapeptase) have been tested on small sample sizes only, with no long-term safety data, and hence have not been widely accepted. Oxytocin, due to its role in inducing the milk-ejection reflex, has also been proposed as an efficacious agent for the relief of postpartum breast engorgement. Other modalities, such as ultrasound therapy, acupuncture, acupressure, massage, hot and cold packs and herbal compresses have also been explored. However, the benefit of some of these treatments has been questioned (Chiu 2010). Cold packs have been identified as a cause of reduced blood flow, and warm packs a trigger of aggravated swelling. A popular form of treatment of breast engorgement is the application of cabbage leaves. Even though no active pharmacological substance in cabbage leaves has been identified in the literature, its convenient shape, low cost, wide availability and purportedly soothing effect make it a sought after treatment. It is also used to treat pain and swelling in other areas of the body, such as for the treatment of osteoarthritis of the knee (Lauche 2016). Reverse pressure softening, a technique that uses gentle positive pressure with the finger-tips to soften the areola, has been shown to improve attachment of the infant to the breast (Cotterman 2004), making it a potential technique for preventing breastfeeding problems during engorgement, but this has not been studied. Hence, there is a need to test reverse pressure softening in a randomised controlled setting.

Current recommendations for the treatment of breast engorgement include various measures aimed at emptying the breast sufficiently to alleviate discomfort, facilitate breastfeeding and prevent complications. These include applying moist heat to the breast prior to feeding to aid oxytocin uptake, frequent feeding, softening the areola prior to attachment, correct positioning and attachment of the baby to the breast during breastfeeding (Mass 2004), gentle massage immediately before and during feeding, and applying cold compresses after feeding (Core Curriculum 2013), along with analgesics (e.g. paracetamol) and anti-inflammatory medication (e.g. ibuprofen), if needed (ABM 2016). Skilled support aimed at assisting the mother attach her baby to the breast as soon and as often as possible is key in relieving engorgement and sustaining breastfeeding. If breastfeeding is not possible, frequent hand-expressing or pumping milk to comfort is recommended, along with other symptomatic measures.

In some countries, such as Sweden, oxytocin spray use to be used routinely in an attempt to enhance drainage of engorged breasts. A postal survey conducted in 2001 of all 57 breastfeeding clinics in Sweden, revealed that oxytocin spray, unrefined cotton wool (as a comfort measure) and acupuncture were used by 87%, 72% and 56% of responding clinics, respectively, for the treatment of breast inflammatory conditions (Kvist 2004). In other countries, such as Taiwan, cold therapies for breast engorgement are discouraged during the month following delivery. Instead, milk expression after the application of hot packs is widely used, as are traditional Chinese therapies, such as Gua Sha scraping therapy. In Japan,

Oketani breast massage, a connective tissue massage developed by the midwife Sotomi Oketani, and performed by specially trained masseurs, is a popular practice among lactating Japanese women. It has been shown to affect the composition of breast milk, increasing the lipid content (Foda 2004).

How the intervention might work

Ideally, treatment of breast engorgement should: 1) provide rapid relief of breast pain; 2) enable successful attachment of the baby to the breast; 3) facilitate efficient drainage of milk from the breasts; and 4) prevent known complications such as mastitis and breast abscess. Optimal treatment should rapidly result in relatively soft, non-tender breasts from which the mother can easily and successfully feed her infant. Numerous treatments have been studied in an attempt to achieve these goals. The interventions studied in this review are based on the following assumptions:

1. administration of *exogenous (external)* oxytocin: release of *endogenous (internal)* oxytocin, from the posterior pituitary gland, is known to cause contraction of the mammary myoepithelial cells, which surround milk-producing alveoli, resulting in expulsion of milk towards the nipple, known as the milk-ejection reflex. In engorgement, the milk-ejection reflex may be inhibited due to vascular congestion in the breast preventing oxytocin from reaching the myoepithelial cells;
2. acupuncture: the stimulation of certain acupuncture points along the skin of the body with acupuncture needles is believed, according to traditional Chinese medicine (TCM), to relieve obstructions in the flow of energy, enabling the body to heal, leading to improved microcirculation and flow of milk;
3. scraping therapy (*Gua-Sha*): the stimulation of acupoints, using a scraping motion on the skin, is believed, according to TCM, to improve circulation and metabolism by removing obstructions and revitalising meridians. In TCM, 14 channels of energy, known as *meridians*, are believed to run throughout the body. Meridians passing just under the skin surface present acupoints;
4. thermal (continuous) ultrasound therapy: it is thought treatment may facilitate the removal of milk from the engorged breast by facilitating milk let-down, leading to less pain and hardness;
5. non-thermal (pulsed) ultrasound therapy: relief of engorgement is attributed to its property of improved cell membrane permeability, through acoustic streaming, bubble formation and microstreaming, thereby facilitating venous and lymphatic drainage of the breasts;
6. enzyme therapy: believed to be able to suppress inflammation, abate and alleviate pain and oedema and accelerate the circulation of blood and lymph;
7. anti-inflammatory medication: known to reduce symptoms of inflammation, such as pain, redness and swelling, therefore assumed to relieve the symptoms of engorgement;
8. cabbage leaves: sulphur compounds, found in cabbage leaves, may increase skin penetration by plant constituents, such as flavonoids, leading to the apparent anti-inflammatory and anti-oedematous effect. Leaves are usually applied chilled, which induces vasoconstriction and further decreases oedema;
9. cold packs: the application of cold is thought to be soothing and to decrease the blood flow to the skin by vasoconstriction, which in turn is believed to decrease engorgement;

10. massage: gentle breast massage is thought to induce the milk-ejection reflex, mobilise the milk and hence reduce the symptoms of breast engorgement;

11. herbal compresses: various herbs (hollyhock, marshmallow, ginger, cactus, aloe, turmeric, and camphor) are thought to have a variety of natural active ingredients with anti-inflammatory, bactericidal and analgesic effects.

Why it is important to do this review

Breastfeeding is the normal way to feed infants, resulting in optimal growth and development. It provides a stimulus for the bonding process between a mother and her baby, as well as protecting them both from disease. A mother's choice to breastfeed is often hampered by breastfeeding difficulties. Breast engorgement is a common condition affecting up to half of all women who choose to breastfeed (Hill 1994). Apart from causing distressing symptoms for the mother, it can lead to serious complications for the mother and baby including the premature cessation of breastfeeding. Earlier systematic reviews on this topic have found insufficient evidence on effective treatments for breast engorgement but, in the interim, several new studies have been reported which may assist in finding an effective treatment for this troubling condition. Additionally, in the era of HIV, exclusive breastfeeding has received attention in an effort to prevent mother-to-child transmission. Failure to identify the best forms of treatment of breast engorgement may result in women mixing breast and formula feeding, thus increasing their risk of HIV transmission.

This Cochrane systematic review is an update of the one first published by Snowden 2001, and subsequently re-published in 2010 and 2016. The previous reviews called for robust research to address the lack of evidence for the treatment of breast engorgement. This review seeks to evaluate current evidence on the best forms of treatment available.

OBJECTIVES

To determine the effectiveness and safety of different forms of treatment for breast engorgement in breastfeeding women.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised and quasi-randomised (method of allocating participants to a treatment that is not strictly random, e.g. by date of birth, hospital record number, alternation) controlled trials evaluating treatments for breast engorgement in breastfeeding women. Cluster-randomised trials were eligible for inclusion. Cross-over trials were not eligible for inclusion.

Studies reported in abstract form were eligible for inclusion, provided that there was sufficient information to allow assessment of eligibility and risk of bias; if information provided in abstracts was insufficient, we tried to contact study authors for more information, or failing that, studies were classified as 'awaiting assessment' until publication of the full trial report.

Types of participants

All women receiving any treatment for breast engorgement during breastfeeding. Breast engorgement was defined by study authors

and may include “lactating women with inflammatory symptoms of the breast” ([Kvist 2004](#)), “puerperal milk stasis” ([Meng 2015](#)) and “breast hyperemia” ([Kamali Moradzade 2013](#)).

Types of interventions

Any interventions intended to treat symptoms of breast engorgement were eligible for inclusion in the review, including (but not limited to):

1. Non-medical forms of treatment (acupuncture, cabbage leaves)
2. Medical treatments (oxytocin, protease)
3. Medical and non-medical forms of treatment combined
4. Information and advice on breastfeeding

Types of outcome measures

Primary outcomes

1. Breast pain (as described by trial authors) (not prespecified)
2. Breast induration/hardness (as described by trial authors) (not prespecified)
3. Breast swelling (as described by trial authors) (not prespecified)
4. Breast engorgement (as described by trial authors) (not prespecified)

Secondary outcomes

1. Pyrexia
2. Mastitis
3. Breast abscess
4. Maternal opinion of treatment
5. Analgesic requirement
6. Hospital admission
7. Woman's confidence in continuing to breastfeed
8. Cessation of breastfeeding
9. Number of women with adverse events

Search methods for identification of studies

The following methods section is based on a standard template used by Cochrane Pregnancy and Childbirth.

Electronic searches

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (2 October 2019).

The Register is a database containing over 25,000 reports of controlled trials in the field of pregnancy and childbirth. It represents over 30 years of searching. For full current search methods used to populate Pregnancy and Childbirth's Trials Register, including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings; and the list of journals reviewed via the current awareness service, please follow this [link](#).

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);

2. weekly searches of MEDLINE (Ovid);
3. weekly searches of Embase (Ovid);
4. monthly searches of CINAHL (EBSCO);
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set that has been fully accounted for in the relevant review sections ([Included studies](#); [Excluded studies](#); Studies awaiting classification; [Ongoing studies](#)).

In addition, we searched [ClinicalTrials.gov](#) and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing trial reports (2 October 2019) using the search methods detailed in [Appendix 1](#).

Searching other resources

We searched the reference lists of retrieved studies.

We did not apply any language or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, see [Mangesi 2016](#).

For this update, the following methods were used for assessing the reports that were identified as a result of the updated search.

The following methods section is based on a standard template used by Cochrane Pregnancy and Childbirth.

Selection of studies

Two review authors (IZG and FS), one of whom is a content expert (IZG), independently assessed all the studies identified as a result of the search strategy to decide whether they met the inclusion criteria. We resolved any disagreements through discussion. We contacted trial authors for additional information where necessary.

Data extraction and management

We used the standard Cochrane Pregnancy and Childbirth Group data extraction template to extract data from the eligible studies. Both review authors independently extracted the data using the agreed form. We resolved discrepancies through discussion. We entered data into Review Manager software ([RevMan 2014](#)) and cross-checked them for accuracy.

Where information regarding any of the identified studies was unclear or incomplete, we attempted to contact authors of the original reports to provide further details. Correspondence requesting further information was sent to nine author teams. We managed to establish contact with authors of four reports ([Batista 2014](#); [Ketsuwan 2018](#); [Kvist 2004](#); [Kvist 2007](#)). Through the

kind assistance of members from Cochrane Iran, we managed to translate two reports written in Farsi (Dehghani 2017; Monazzami 2019) and extract necessary data.

Assessment of risk of bias in included studies

Both review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019). We resolved any disagreement by discussion. The following domains were assessed.

(1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether the intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed the methods as:

- low risk of bias (less than 10% missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; `as treated` analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we had about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high overall risk of bias, according to the criteria given in the *Handbook* (Higgins 2019). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings. We planned to explore

the impact of the level of bias through undertaking sensitivity analyses, but were unable to do this due to too few studies included in any single analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. In future updates, if necessary, we will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We had planned to include cluster-randomised trials but we identified none. In future updates of this review, if we identify any eligible cluster-randomised trials, we will include them in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Handbook [Section 16.3.4 or 16.3.6]* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Other unit of analysis issues

Several of the studies included in the review used breasts rather than women as the unit of analysis (McLachlan 1991; Roberts 1995a; Roberts 1995b). We are aware that a woman's breasts (engorged or not) are unlikely to be independent of each other and such non-independent data require special methods of analysis (Kvist 2007). In this version of the review, data were not presented in a way that allowed us to include them in the data tables and so we have presented a brief narrative description of results. If usable data become available in the future, we will seek statistical help with analysis.

Dealing with missing data

We obtained missing data from a number of study authors (see [Characteristics of included studies](#) for details).

For included studies, we noted levels of attrition.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all

participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We were unable to combine results in meta-analyses because so few trials contributed data and each examined different interventions. In future updates of the review if more data are added, we plan to assess heterogeneity among trials. We will assess statistical heterogeneity in each meta-analysis using the I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if an I^2 is greater than 50% and there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

In future updates, if there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We could not combine results from trials due to different interventions being evaluated. In future updates, if more data are available, we plan to use fixed-effect meta-analysis for combining data.

In future updates, where data are suitable for meta-analysis, we will use the random-effects model where there is statistical heterogeneity and clinical heterogeneity such that the differences between study results may be attributed to a combination of chance and true variation in the intervention effects.

Subgroup analysis and investigation of heterogeneity

We were unable to combine any of the studies to allow us to do subgroup analysis because studies were few and they evaluated different interventions.

In future updates of this review, if data do become available, we will carry out subgroup analysis for primary outcomes to investigate whether the effects of interventions are different in the following groups of women.

1. Women who delivered spontaneously and those who delivered by caesarean section
2. Primiparous and multiparous women

We will assess subgroup differences by interaction tests available within RevMan (RevMan 2014). We will report the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

In this version of the review, we included too few studies (examining several different types of interventions) to allow meaningful sensitivity analysis. In future updates, if sufficient data are available we will carry out sensitivity analysis to investigate if removing trials at high risk of bias from the analysis substantially changes the effect estimate.

Summary of findings and assessment of the certainty of the evidence

We assessed the certainty of evidence using the GRADE approach as outlined in the [GRADE handbook](#). We created 'Summary of findings' tables of narrative results for the following comparisons:

- Cabbage leaf treatments versus other treatments/placebo
- Compress treatments versus other treatments/routine care
- Medical treatments versus placebo
- Cold gel packs versus routine care
- Massage-based therapies versus other treatments/routine care
- Other treatments versus other treatments/advice/routine care

The following outcomes are presented in our narrative 'Summary of findings' tables:

1. Breast pain
2. Breast induration/hardness
3. Breast swelling

4. Breast engorgement
5. Maternal opinion of treatment
6. Breastfeeding cessation
7. Number of women with adverse events

The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence for each outcome. The evidence can be downgraded from 'high certainty' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

RESULTS

Description of studies

Results of the search

See: [Figure 1](#)

Figure 1. Study flow diagram.

We retrieved 22 new trial reports from the updated search, of which three were excluded with reasons and four are ongoing studies. The

remaining 15 reports were related to eight new trials, which were included for analysis.

Included studies

In total, we included 21 studies (2170 women randomised), of which 12 studies were conducted between 1951 and 2018, whereas the remaining nine studies did not report recruitment dates.

Setting

Studies were conducted in a variety of settings, from Iran to Australia, undertaking four studies each, followed by Sweden, where three studies took place, whereas in Singapore and India two studies in each country were conducted. Countries that contributed one study are: USA, Japan, China, Brazil, Taiwan and Thailand.

Funding and declarations of interest

Three out of 21 studies were funded by an agency with a commercial interest, three received charitable funding, four received no funding, six were funded by government institutions and six author teams did not declare their funding source. Over half of the study reports did not contain any declarations of interest, while the remaining author teams declared that they had no conflicts of interest.

Sample size

Sample sizes varied greatly, with the smallest study recruiting 16 participants (Batista 2014) and the largest study involving 500 women (Ketsuwan 2018). Only three other studies included 200 or more participants (Kvist 2007; Meng 2015; Wong 2017), with the remaining trials recruiting 109 women or fewer. Of the total number of studies, one-third had fewer than 50 participants.

Duration of treatment and follow-up

Duration of treatment varied from seconds, where oral medication or subcutaneous injections were administered, to eight hours, where chilled cabbage leaves or gel packs were applied. Herbal compresses were usually placed on the breasts for approximately half an hour, whereas ultrasound therapy was applied for up to 15 minutes, depending on breast size. Some treatments were given once only, e.g. massage therapy, acupuncture, cabbage leaves/extract, whereas other treatments were administered over the course of up to seven days, e.g. medication, hollyhock, aloe and cactus, ultrasound, cold packs. Follow-up varied between 15 minutes, e.g. following electromechanical or manual massage (Batista 2014), and six months (Wong 2017), e.g. following application of cabbage leaves or cold pack or standard care (to determine breastfeeding duration). The majority of studies observed participants for two to seven days, or until symptoms subsided, with the remaining studies assessing participants after two to eight hours, e.g. after application of cabbage leaves or cabbage extract.

Interventions

All of the included studies focused on women with symptoms and signs of breast engorgement, although definitions of breast engorgement and inclusion criteria varied, demonstrating a lack of a standard approach in diagnosing this condition. In most of the studies, women with swollen, hard, painful breasts (with or without difficulty breastfeeding) were recruited; whereas in some studies women with increased body temperature and localised redness were also included, suggesting a diagnosis of mastitis. Most participants were recruited on hospital postnatal wards, whereas in the studies by Kvist (Kvist 2004; Kvist 2007) women were recruited

at breastfeeding clinics, therefore may have been breastfeeding for some time. The majority of women were seen within two weeks of giving birth. In one study, the focus was specifically on women who had caesarean births (Robson 1990) and, in another, on women who sought care at a human milk bank (Batista 2014). Of the total number of studies, six were conducted in multiple sites (Dehghani 2017; Khosravan 2017; Kvist 2004; Roberts 1995a; Roberts 1995b; Roberts 1998), the remaining being single-centre studies.

The studies we have included in the review examined the effects of a broad range of interventions, including:

1. acupuncture versus usual care (Kvist 2004; Kvist 2007);
2. acupressure versus hot and cold compresses (Kamali Moradzade 2013);
3. cabbage leaves (cold versus room temperature leaves (Roberts 1995b); chilled cabbage leaves versus chilled gel packs (Roberts 1995a); cabbage leaf extract versus placebo (Roberts 1998); room temperature cabbage leaves versus hot water bag (Kumari 2019); cold cabbage leaves versus cold gel packs or routine care (Wong 2017));
4. cold packs versus routine care (Robson 1990; Wong 2017);
5. protease complex tablets versus placebo (Murata 1965);
6. ultrasound versus sham ultrasound (McLachlan 1991);
7. ultrasound plus massage versus massage only (Sankanagoudar 2011);
8. serrapeptase versus placebo (Kee 1989);
9. Gua-Sha (scraping) therapy versus hot packs and massage (Chiu 2010);
10. subcutaneous oxytocin versus placebo (Ingelman-Sundberg 1953);
11. electromechanical breast massage followed by mechanical pumping versus manual breast massage followed by manual pumping (Batista 2014);
12. Oketani breast massage versus routine care (Dehghani 2017);
13. herbal compress versus hot compress (Ketsuwan 2018);
14. hot and cold compress plus hollyhock leaves compress versus hot and cold compress (Khosravan 2017);
15. warm ginger compress versus routine care (Monazzami 2019);
16. cold cactus/aloe compress and breast massage versus cactus/aloe compress only (Meng 2015);
17. cold cactus/aloe compress and breast massage versus breast massage only (Meng 2015);
18. cold cactus/aloe compress versus breast massage (Meng 2015).

The broad range of interventions studied meant that we were not able to pool data from more than one study in any of the analyses.

Further details on the women participating in the included studies and descriptions of the interventions can be found in the [Characteristics of included studies](#) tables.

Excluded studies

We excluded twelve studies (13 reports) identified by the search strategy. The main reasons for exclusion were that studies examined the prevention of breast engorgement (KCT0002436; Nikodem 1993) in women whose breasts were not yet engorged, or examined interventions to suppress lactation in women who did not intend to breastfeed, rather than examining interventions

to treat the symptoms of engorgement in women who were breastfeeding their babies (Booker 1970; Filteau 1999; Garry 1956; King 1958; Phillips 1975; Roser 1966; Ryan 1962). One study, that was otherwise eligible for inclusion, was excluded because not all of the women recruited were receiving an intervention to treat breast engorgement (Stenchever 1962). Another study was excluded because it did not have a comparison group (NCT032307602017). Finally, the study by Gao and colleagues (Gao 2018) was excluded because it reported on the treatment of blocked ducts (using milk duct probing) rather than breast engorgement.

Approximately half of the women recruited in the Nikodem 1993 study did not have symptoms of breast engorgement and the intervention aimed to prevent rather than treat symptoms in these women. Separate results were not available for women with engorged breasts seeking symptom relief. We have provided further information on these studies in the [Characteristics of excluded studies](#) tables.

Risk of bias in included studies

Please see [Figure 2](#) and [Figure 3](#) for a summary of 'Risk of bias' assessments.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Random sequence generation

We judged seven trials as having low risk of bias for random sequence generation (Chiu 2010; Ketsuwan 2018; Kvist 2004; Kvist 2007; McLachlan 1991; Roberts 1998; Wong 2017) because they used robust randomisation methods, such as coin tossing or computer-generated random numbers.

Even after contacting authors for clarification of potential selection bias, adequacy of random sequence generation remained unclear in nine out of 21 studies (Dehghani 2017; Kamali Moradzade 2013; Kee 1989; Khosravan 2017; Kumari 2019; Meng 2015; Monazzami 2019; Roberts 1995a; Sankanagoudar 2011) with most authors providing insufficient information (e.g. "subjects were randomly divided").

We assessed five trials as having high risk of selection bias for random sequence generation. Quasi-randomisation was used in these four trials: group allocation was by odd or even case-note number in the Ingelman-Sundberg 1953 trial, by day of the week in the Murata 1965 trial, and by hospital number in the in the Roberts 1995b study. Although coin toss was used as an adequate method for initial random sequence generation in the Batista 2014 study, intervention options were alternated thereafter, placing this study at high risk of selection bias. Finally, in the study by Robson 1990 there were serious problems with the way randomisation was carried out; a table of random numbers was used to decide the randomisation sequence but the allocation sequence was not necessarily observed, so, for example, women with the most distressing symptoms assigned to the control group were moved into the intervention group, and there was no intention-to-treat analysis.

Allocation concealment

In four studies, we judged that the methods used to conceal group allocation were adequate and therefore low risk; in these studies, group assignments were concealed in sealed opaque sequentially numbered envelopes (Ketsuwan 2018; Kvist 2004; Kvist 2007; Wong 2017).

We judged four trials as high risk for allocation concealment (Batista 2014; Ingelman-Sundberg 1953; Murata 1965; Roberts 1995b) because their methods of treatment allocation were such that it was easy to predict which groups the women would be assigned to. In all of the remaining studies, methods to conceal allocation were reported in a way that was unclear to make a judgement and were therefore assessed as having unclear risk of bias.

Blinding of participants and personnel (performance bias)

Blinding of participants and personnel was judged as the domain with the highest risk of bias, with 16 studies falling into this category. Given the nature of the studies, where different types of interventions were often compared, blinding participants and personnel was not always feasible and hence not attempted (Batista 2014; Chiu 2010; Dehghani 2017; Kamali Moradzade 2013; Ketsuwan 2018; Khosravan 2017; Kumari 2019; Kvist 2004; Kvist 2007; Meng 2015; Monazzami 2019; Roberts 1995a; Roberts 1995b; Robson 1990; Sankanagoudar 2011; Wong 2017).

In the study by Ketsuwan and colleagues (Ketsuwan 2018), even though nursing staff made an effort to mimic the hot herbal balls

placed against the mothers' breasts by creating similar ball-like towels and applying them in the same manner, it is very unlikely that participants, who were also the outcome assessors, would have remained blinded to group allocation given the fragrances of the volatile active herbal ingredients (ginger, turmeric and camphor). Hence, this study was assessed as having high risk of performance and detection bias.

Four studies were assessed as having low risk of performance bias (Ingelman-Sundberg 1953; Kee 1989; McLachlan 1991; Roberts 1998), because adequate measures, such as identical placebo tablets, were taken to blind the participants and the personnel involved.

One study (Murata 1965) used placebo tablets in the comparator group but it was not clear if the active intervention and the placebo were identical or whether the women would be able to know which treatment they were receiving. We judged this trial to be at unclear risk of performance bias because of this lack of information.

Blinding of outcome assessors (detection bias)

Thirteen out of 21 studies were assessed as having high risk of bias for blinding of outcome assessors (Dehghani 2017; Kamali Moradzade 2013; Ketsuwan 2018; Khosravan 2017; Kumari 2019; Kvist 2004; Kvist 2007; Meng 2015; Monazzami 2019; Roberts 1995a; Roberts 1995b; Robson 1990; Wong 2017). The lack of blinding in these studies may represent a serious source of bias, as many of the outcomes measured (subjective views about treatment and assessment of symptoms) may have been influenced by knowledge of treatment assignment.

Five studies were judged as having low risk of detection bias (Kee 1989; McLachlan 1991; Roberts 1998; Chiu 2010; Murata 1965). Most of these studies used placebo methods: in Murata 1965, protease complex tablets were compared with lactose-containing placebo tablets; in the Ingelman-Sundberg 1953, subcutaneous oxytocin was compared with physiological saline injections; in Kee 1989, oral serrapeptase was compared with specially made control tablets that were identical in appearance and given according to the same regimen; and in the Roberts 1998 trial a cream containing cabbage leaf extract was compared with a base/placebo cream, with rosewater added to both creams to camouflage the residual odour of cabbage. Blinding of outcome assessors was not reported in three studies, so we assessed these as having unclear risk of detection bias (Batista 2014; Ingelman-Sundberg 1953; Sankanagoudar 2011).

Incomplete outcome data

We judged that the level of attrition bias was unclear in three studies: an older study (Ingelman-Sundberg 1953), which did not mention how incomplete outcome data were addressed, in the study by Batista 2014, where the final sample size was more than 10-fold smaller than the calculated sample size, and in a more recent study (Dehghani 2017) where reasons were not given for loss of a small number of participants. Four studies were assessed as having high risk of attrition bias (Kvist 2004; McLachlan 1991; Meng 2015; Robson 1990) as information on loss to follow-up, or denominators in the results section, may not have been explicit. For example, in the Meng study (Meng 2015), 48 participants were lost to follow-up and not accounted for. No or minimal attrition was found in the following studies: Chiu 2010; Kamali Moradzade 2013; Kee 1989; Ketsuwan 2018; Khosravan 2017; Kumari 2019; Kvist

2007; Monazzami 2019; Murata 1965; Roberts 1995a; Roberts 1995b; Roberts 1998; Sankanagoudar 2011 and Wong 2017.

Selective reporting

We did not have study protocols for all the trials to adequately assess within-study selective reporting bias. For these studies, we assessed selective reporting bias by comparing what was listed in the methods section of the study with what was reported in the results section. Most studies (Chiu 2010; Dehghani 2017; Kamali Moradzade 2013; Kee 1989; Ketsuwan 2018; Khosravan 2017; Kumari 2019; Kvist 2007; McLachlan 1991; Meng 2015; Monazzami 2019; Murata 1965; Roberts 1995b; Roberts 1995a; Robson 1990; Sankanagoudar 2011; Wong 2017) reported outcomes that were pre-stated in the protocol/methods section and on outcomes of interest in this review. There was an unclear risk of bias in two studies: Roberts 1998 because whilst the authors have mentioned the outcomes they intended to assess, they presented the results with the two groups combined; in Ingelman-Sundberg 1953, the authors report their outcomes in percentages, not in numbers out of the totals, which made it difficult to determine the denominators. Kvist 2004 carries a risk of bias as the authors mentioned that the study had to be stopped prematurely but no data were given. Also, they did not mention in the results one of the outcomes (resistance of breast tissue), which was listed in the methods' section. Other outcomes were mentioned, as non-significant results, but were not reported adequately. In the study by Batista 2014, participants were evaluated based on clinical exam and thermography but only thermography was reported for both groups, placing this study at high risk of reporting bias.

Other potential sources of bias

Of a total of 21 studies, nine were assessed as having high risk of other sources of bias. There was considerable baseline imbalance in the study by Robson 1990. Women in the control group had much lower pre-test pain scores. There was also some deviation from protocol in this study: three women who were described as having "heightened distress levels" assigned to the intervention group were moved into the control group as this was perceived as being less demanding of their time, and one mother with severe discomfort asked to be assigned to the intervention group. In all, the randomisation schedule was not observed in eight cases. There was also no intention-to-treat analysis. This represents a serious source of bias. In another study (Roberts 1998), a significant baseline imbalance was found in the number of primiparas. Authors were contacted but no explanation was found. This may have been due to chance or a small sample size but may also have been due to possible problems with allocation concealment or compromised blinding, hence we made a judgement of possible high risk of bias. There was considerable risk of bias in Batista 2014; no baseline characteristics were provided for included participants, although varying degrees of engorgement were alluded to, implying the possibility of baseline imbalance. Additionally, the study was severely underpowered, limiting its precision. No statement of conflict of interest or sponsorship was provided, raising the possibility of industry funding.

In the remaining six studies, assessment and analysis was at the level of breasts rather than women (Dehghani 2017; Kamali Moradzade 2013; McLachlan 1991; Monazzami 2019; Roberts 1995a; Roberts 1995b). McLachlan 1991 stated that in their study, when the visual analogue scale was used, it was not always easy for women

to make a clear distinction between the left and right breast. This may be an indication that having an individual breast as a unit of analysis is not ideal. In the studies, there was no adjustment made for the non-independence of breasts, and we found interpretation of results difficult. This difficulty was exacerbated in the study by Roberts 1995a, because the pre-test rating of symptoms was for both breasts together (an overall rating), whereas at post-test, women provided ratings for separate breasts. It was, therefore, not possible for us to understand the possible differences between pre- and post-test scores.

In one study (Kvist 2004), insufficient information was available, due to lack of clarity in reporting, to assess whether an important risk of bias existed. In the Khosravan study (Khosravan 2017), some participants were excluded for not having performed the intervention properly, which raised the possibility of bias. In the Murata 1965 and Kee 1989 studies, the active tablets used in the trial were supplied by a pharmaceutical company, hence it was unclear whether a vested interest may have influenced study results.

Effects of interventions

See: [Summary of findings 1 Cabbage leaf treatments versus other treatments/placebo for breast engorgement during lactation](#); [Summary of findings 2 Compress treatments versus other treatments/routine care for breast engorgement during lactation](#); [Summary of findings 3 Medical treatments versus placebo for breast engorgement](#); [Summary of findings 4 Cold gel packs versus routine care for breast engorgement during lactation](#); [Summary of findings 5 Massage-based therapies versus other treatments/routine care for women with breast engorgement during lactation](#); [Summary of findings 6 Other treatments versus other treatments/advice/routine care for women with breast engorgement during lactation](#)

We included 21 studies with 2170 women, of whom 209 were analysed at the individual breast level (Kamali Moradzade 2013; McLachlan 1991; Monazzami 2019; Roberts 1995a; Roberts 1995b). We were unable to pool any results from studies in meta-analysis because of the broad range of interventions examined, and the way in which outcomes were assessed and reported in these trials. We have set out separate comparisons for each type of intervention in the text below, and in the data tables; in some studies, we were not able to include all outcome data in tables because of the form in which results were presented in research reports; for these outcomes, we provide a brief description of findings as reported by the trial authors.

Comparison one: cabbage leaf treatments versus other treatments/placebo

Five studies examined cabbage leaves or cabbage extract to reduce symptoms of breast engorgement (Kumari 2019; Roberts 1995a; Roberts 1995b; Roberts 1998; Wong 2017). Four studies assessed the use of cabbage leaves: chilled versus room temperature cabbage leaves (Roberts 1995a); chilled cabbage leaves versus chilled gel packs (Roberts 1995b); room temperature cabbage leaves versus hot water bag (Kumari 2019); and cold cabbage leaves versus either routine care or cold gel packs (Wong 2017).

Another study evaluated the use of cabbage leaf extract, in the form of a cream, versus placebo (Roberts 1998).

In two studies ([Roberts 1995a](#) [Roberts 1995b](#)), breasts rather than women were randomised, and results were not reported in a way that allowed us to enter data into [RevMan 2014](#).

Primary outcomes

Breast pain (as described by trial authors) (not prespecified)

The studies measured breast pain on a 0-10 visual analogue scale (VAS) where a higher score signified greater pain.

We are uncertain if there is any difference between room temperature cabbage leaves and hot water bags in terms of reducing breast pain (mean difference (MD) -0.16, 95% confidence interval (CI) -0.39 to 0.07; $n = 63$; [Analysis 1.1.1](#); [Summary of findings 1](#); very low-certainty evidence; [Kumari 2019](#)).

Cold cabbage leaves may reduce breast pain more than routine care (MD -1.03, 95% CI -1.53 to -0.53; $n = 152$) or cold gel packs (MD -0.63, 95% CI -1.09 to -0.17; $n = 151$) but the certainty of evidence is very low ([Analysis 1.1.2](#) and [Analysis 1.1.3](#); [Summary of findings 1](#); very low-certainty evidence; [Wong 2017](#)).

In one study, comparing cold versus room temperature cabbage leaves ([Roberts 1995a](#)), authors reported very slightly lower pain scores for cold cabbage leaves but the data were reported in a way that was unsuitable for analysis.

We are uncertain if there is any difference between cabbage leaf extract cream and placebo cream (MD 0.40, 95% CI -0.67 to 1.47; $n = 39$; [Analysis 1.1.4](#); [Summary of findings 1](#); very low-certainty evidence; [Roberts 1998](#)).

In the study comparing chilled cabbage leaves and chilled gel packs ([Roberts 1995b](#)), it was reported that women in both groups had significant reductions in pain scores following treatment (30% for the cabbage leaves and 39% for the gel packs), but that there were no differences between groups (data not shown). While both treatments appeared to produce some alleviation of discomfort, it is likely that the subjective ratings on the pain ruler were susceptible to a placebo effect.

Breast induration/hardness (as described by trial authors) (not prespecified)

The studies measured breast hardness on a 1-6 breast engorgement assessment scale, where higher scores signified greater hardness.

Cold cabbage leaves may reduce breast hardness more than routine care (MD -0.58, 95% CI -0.82 to -0.34; 152 women; [Analysis 1.2.1](#); [Summary of findings 1](#); low-certainty evidence; [Wong 2017](#)). There may be little or no difference between cold cabbage leaves and cold gel packs in terms of breast hardness (MD -0.24, 95% CI -0.48 to -0.00; 151 women; [Analysis 1.2.2](#); [Summary of findings 1](#); low-certainty evidence; [Wong 2017](#)).

Breast swelling (as described by trial authors) (not prespecified)

Not reported.

Breast engorgement

The studies measured breast engorgement on a 1-6 breast engorgement assessment scale, where higher scores signified greater hardness.

Room temperature cabbage leaves may reduce breast engorgement more than hot water bag (MD -1.16, 95% CI -1.36 to -0.96; 63 women; [Analysis 1.3.1](#); [Summary of findings 1](#); very low-certainty evidence; [Kumari 2019](#)).

There may be little or no difference between cabbage leaf extract cream and placebo cream with regard to breast engorgement (MD 0.20, 95% CI -0.18 to 0.58; 39 women; [Analysis 1.3.2](#); [Summary of findings 1](#); low-certainty evidence; [Roberts 1998](#)).

Secondary outcomes

Pyrexia

Not reported.

Mastitis

Not reported.

Breast abscess

Not reported.

Maternal opinion of treatment

Based on one study ([Wong 2017](#)), more women may be satisfied or very satisfied with cold cabbage leaves than with routine care (risk ratio (RR) 1.42, 95% CI 1.22 to 1.63; 152 women; [Analysis 1.4.1](#)) or than with cold gel packs (RR 1.23, 95% CI 1.10 to 1.38; 152 women; [Analysis 1.4.2](#); [Summary of findings 1](#); low-certainty evidence).

Analgesic requirement

Not reported.

Hospital admission

Not reported.

Woman's confidence in continuing to breastfeed

Not reported.

Cessation of breastfeeding

It is uncertain whether more women stop breastfeeding after treatment with cold cabbage leaves compared to routine care, or cold cabbage leaves compared to cold gel packs, because the certainty of evidence is low and the 95% CIs are consistent with both important benefit and important harm ([Analysis 1.5](#); [Summary of findings 1](#); [Wong 2017](#)).

Number of women with adverse events

Not reported.

Comparison two: compress treatments versus other treatments/routine care

One study compared hot compress made with herbs to hot compress without herbs ([Ketsuwan 2018](#)), another compared warm compresses followed by hollyhock leaf compress to warm compress alone ([Khosravan 2017](#)), another compared warm ginger compress to routine care ([Monazzami 2019](#)) and a fourth study compared cactus and aloe cold compress to massage therapy ([Meng 2015](#)).

Primary outcomes

Breast pain (as described by trial authors) (not prespecified)

The studies measured breast pain on a 0-10 visual analogue scale (VAS) where a higher score signified greater pain.

Herbal compresses may reduce breast pain more than hot compresses without herbs (MD -1.80, 95% CI -2.07 to -1.53; 500 women; [Analysis 2.1.1](#); [Summary of findings 2](#); low-certainty evidence).

There may be little or no difference in breast pain between cactus and aloe cold compress and massage therapy (MD 0.17, 95% CI -0.55 to 0.89; 102 women; [Analysis 2.1.2](#); [Summary of findings 2](#); low-certainty evidence).

Cactus and aloe cold compress plus massage therapy may reduce breast pain more than massage therapy alone (MD -1.27, 95% CI -1.75 to -0.79; 100 women; [Analysis 2.1.3](#); [Summary of findings 2](#); low-certainty evidence).

Breast induration/hardness (as described by trial authors) (not prespecified)

Cactus and aloe cold compress may reduce the risk of breast hardness more than massage therapy (RR 0.66, 95% CI 0.51 to 0.87; 102 women; [Analysis 2.2.1](#); [Summary of findings 2](#); low-certainty evidence; [Meng 2015](#)).

Adding cactus and aloe cold compress to massage therapy may reduce the risk of breast hardness more than massage therapy alone (RR 0.38, 95% CI 0.25 to 0.58; 100 women; [Analysis 2.2.2](#); [Summary of findings 2](#); low-certainty evidence; [Meng 2015](#)).

Breast swelling (as described by trial authors) (not prespecified)

Not reported.

Breast engorgement

One study measured breast engorgement on a 0-19 breast engorgement assessment scale, where higher scores signified greater extent of engorgement.

It is uncertain if herbal compresses with hollyhock leaf reduce breast engorgement more than warm compresses without hollyhock leaf (MD -2.82, 95% CI -4.60 to -1.04; 40 women; [Analysis 2.3](#); [Summary of findings 2](#); very low-certainty evidence; [Khosravan 2017](#)).

Secondary outcomes

Pyrexia

Not reported.

Mastitis

Not reported.

Breast abscess

Not reported.

Maternal opinion of treatment

Not reported.

Analgesic requirement

Not reported.

Hospital admission

Not reported.

Woman's confidence in continuing to breastfeed

Not reported.

Cessation of breastfeeding

It is uncertain if more women stop breastfeeding within seven days after treatment with cactus and aloe cold compress compared to massage therapy (RR 1.08, 95% CI 0.45 to 2.58; 102 women; [Analysis 2.4.1](#); [Summary of findings 2](#); very low-certainty evidence; [Meng 2015](#)).

Similarly, it is uncertain if more women stop breastfeeding within seven days after treatment with cactus and aloe cold compress plus massage therapy compared to massage therapy alone (RR 0.25, 95% CI 0.06 to 1.12; 100 women; [Analysis 2.4.2](#); [Summary of findings 2](#); very low-certainty evidence; [Meng 2015](#)).

Number of women with adverse events

One study found more women in the herbal compress group had adverse events (skin irritation) compared to the hot compress group (2/250 and 0/250 respectively) but the CIs were consistent with both appreciable harm and benefit (RR 5.00, 95% CI 0.24 to 103.62; 500 women; [Analysis 2.5](#); [Summary of findings 2](#); moderate-certainty evidence; [Ketsuwan 2018](#)).

Comparison three: medical treatments versus placebo

Three trials compared medical treatments to placebo: protease complex (a plant enzyme) ([Murata 1965](#)); subcutaneous oxytocin ([Ingelman-Sundberg 1953](#)); oral serrapeptase (a proteolytic enzyme derived from the silk worm) ([Kee 1989](#)).

Primary outcomes

Breast pain (as described by trial authors) (not prespecified)

Protease may reduce the risk of breast pain more than placebo (RR 0.17, 95% CI 0.04 to 0.74; 59 women; [Analysis 3.1.1](#); [Summary of findings 3](#); low-certainty evidence; [Murata 1965](#)).

There may be little or no difference in the risk of breast pain with serrapeptase compared to placebo (RR 0.56, 95% CI 0.21 to 1.49; 70 women; [Analysis 3.1.2](#); [Summary of findings 3](#); low-certainty evidence; [Kee 1989](#)).

Breast induration/hardness (as described by trial authors) (not prespecified)

Not reported.

Breast swelling (as described by trial authors) (not prespecified)

Protease may reduce the risk of breast swelling more than placebo (RR 0.34, 95% CI 0.15 to 0.79; 59 women; [Analysis 3.1.1](#); [Summary of findings 3](#); low-certainty evidence; [Murata 1965](#)).

There may be little or no difference in the risk of breast swelling with serrapeptase compared to placebo (RR 0.75, 95% CI 0.36 to 1.55; 70 women; [Analysis 3.1.2](#); [Summary of findings 3](#); low-certainty evidence; [Kee 1989](#)).

Breast engorgement

It is uncertain if there is any difference in the risk of breast engorgement with oxytocin compared to placebo (RR 3.13, 95% CI 0.68 to 14.44; 45 women; [Analysis 3.2.1](#); [Summary of findings 3](#); low-certainty evidence; [Ingelman-Sundberg 1953](#)).

Serrapeptase may reduce the risk of breast engorgement more than placebo (RR 0.36, 95% CI 0.14 to 0.88; 70 women; [Analysis 3.2.2](#); [Summary of findings 3](#); low-certainty evidence; [Kee 1989](#)).

Secondary outcomes

Pyrexia

Not reported.

Mastitis

Not reported.

Breast abscess

Not reported.

Maternal opinion of treatment

Not reported.

Analgesic requirement

Not reported.

Hospital admission

Not reported.

Woman's confidence in continuing to breastfeed

Not reported.

Cessation of breastfeeding

Not reported.

Number of women with adverse events

Adverse events were measured and reported in the studies investigating serrapeptase ([Kee 1989](#)) and protease ([Murata 1965](#)). No women in any of the groups experienced adverse events ([Summary of findings 3](#); low-certainty evidence).

Comparison four: cold gel packs versus routine care

Two studies compared cold gel packs to routine care ([Robson 1990](#); [Wong 2017](#)) and another compared cold gel packs to cold cabbage leaves ([Roberts 1995b](#)).

Primary outcomes

Breast pain (as described by trial authors) (not prespecified)

It is uncertain whether cold gel packs reduce breast pain more than routine care or cold cabbage leaves because the certainty of evidence is very low ([Summary of findings 4](#)).

One study found little difference in VAS pain scores between the cold gel pack group and the routine care group (MD -0.40, 95% CI -0.91 to 0.11; 151 women; [Analysis 4.1](#)).

In one study ([Roberts 1995b](#)), women were randomised to receive either cold gel pack treatment on the left breast and cold cabbage

leaves on the right or vice versa. Pain scores were reported per breast so it was not possible to include the data in our analysis.

In one study ([Robson 1990](#)), women in the intervention group seemed to experience a reduction in **pain intensity** post-test. The author reported a decrease in mean **pain intensity** score from 1.84 (SD 0.65) to 1.23 (SD 0.68) compared with an increase in the control group from 1.50 (SD 0.71) to 1.79 (SD 0.72) (data not shown). However, the differences between groups at baseline, and the failure to observe randomisation (women with "heightened distress" were moved into the control group), make results difficult to interpret. It was not possible to include these results in the data and analyses.

Breast induration/hardness (as described by trial authors) (not prespecified)

Cold gel packs may reduce the risk of breast hardness more than routine care (RR -0.34, 95% CI -0.60 to -0.08; 151 women; [Summary of findings 4](#); low-certainty evidence; [Wong 2017](#)).

Breast swelling (as described by trial authors) (not prespecified)

Not reported.

Breast engorgement

Not reported.

Secondary outcomes

Pyrexia

Not reported.

Mastitis

Not reported.

Breast abscess

Not reported.

Maternal opinion of treatment

It is uncertain if more women were satisfied with cold gel pack treatment or routine care (RR 1.17, 95% CI 0.97 to 1.40; 151 women; [Analysis 4.3](#); [Summary of findings 4](#); low-certainty evidence; [Wong 2017](#)).

Two-thirds of 34 women stated that they preferred the cabbage leaves because they gave a more immediate effect, while others felt that the chilled gel packs gave a more lasting effect ([Roberts 1995b](#)).

Analgesic requirement

Not reported.

Hospital admission

Not reported.

Woman's confidence in continuing to breastfeed

Not reported.

Cessation of breastfeeding

It is uncertain if more women stop breastfeeding within six months postpartum following treatment with cold gel packs or with routine care (RR 1.03, 95% CI 0.50 to 2.14; [Analysis 4.4](#); [Wong 2017](#)). The

certainty of evidence is low, the CIs are wide and are consistent with both appreciable harm and benefit ([Summary of findings 4](#)).

Number of women with adverse events

Not reported.

Comparison five: massage-based therapies versus other treatments/routine care

One study ([Batista 2014](#)) compared electromechanical massage with manual massage but none of our prespecified outcomes were reported.

One study compared massage plus cactus and aloe cold compress to cactus and aloe cold compress alone ([Meng 2015](#)).

One study compared Oketani breast massage with routine care ([Dehghani 2017](#)) but the data were reported per breast instead of per woman so the data could not be included in the analysis.

Primary outcomes

Breast pain (as described by trial authors) (not prespecified)

Adding massage therapy to cactus and aloe cold compress may reduce breast pain more than cactus and aloe cold compress alone, according to pain measured by 0-10 VAS (MD -1.44, 95% CI -2.14 to -0.74; 102 women; [Analysis 5.1](#); [Summary of findings 5](#); low-certainty evidence; [Meng 2015](#)).

Breast induration/hardness (as described by trial authors) (not prespecified)

Adding massage therapy to cactus and aloe cold compress may reduce the risk of breast hardness more than cactus and aloe cold compress alone (RR 0.57, 95% CI 0.36 to 0.92; 102 women; [Analysis 5.2](#); [Summary of findings 5](#); low-certainty evidence; [Meng 2015](#)).

Breast swelling (as described by trial authors) (not prespecified)

Not reported.

Breast engorgement

One study found lower breast engorgement scores in women who had Oketani massage than those who had routine care but the data were reported per breast so the true effect is unclear ([Dehghani 2017](#)) ([Summary of findings 5](#); low-certainty evidence).

Secondary outcomes

Pyrexia

Not reported.

Mastitis

Not reported.

Breast abscess

Not reported

Maternal opinion of treatment

Not reported.

Analgesic requirement

Not reported.

Hospital admission

Not reported.

Woman's confidence in continuing to breastfeed

Not reported.

Cessation of breastfeeding

It is uncertain if more women stop breastfeeding following treatment with cactus and aloe cold compress compared with massage therapy, or treatment with massage plus cactus and aloe cold compress compared with cactus and aloe cold compress alone. The certainty of evidence is low and the CIs were wide, indicating that the true effect may be either appreciable harm or benefit ([Summary of findings 5](#); [Analysis 5.3](#); [Meng 2015](#)).

Number of women with adverse events

Not reported.

Comparison six: other treatments (Gua-Sha therapy, acupuncture, acupressure) versus other treatments/advice/routine care

One study compared Gua-Sha therapy (scraping) therapy with hot packs and massage ([Chiu 2010](#)). One study compared acupressure to hot and cold compresses applied intermittently ([Kamali Moradzade 2013](#)). Two studies examined the effects of acupuncture on breast engorgement ([Kvist 2004](#); [Kvist 2007](#)). In both studies, there were three treatment groups: advice and usual care (which might include the use of oxytocin nasal spray at the discretion of the midwife); advice and acupuncture, excluding the SP6 acupoint; and advice and acupuncture, including the SP6 point. Advice consisted of information on breastfeeding frequency, duration and technique, breast emptying, and the application of unrefined cotton wool as needed. In [Kvist 2007](#), the two intervention groups were combined during data analysis as suggested in section 23.3.2 of the *Cochrane Handbook* ([Higgins 2019](#)).

We were unable to include data from the [Kvist 2004](#) study in analyses because results were not set out separately for the three randomised groups in the published report and were not available from the authors. The authors, however, reported that there were no significant differences on day three of treatment between the three groups in the severity index (a sum score for **breast tension, erythema and pain**) or for maternal satisfaction with breastfeeding. The percentage of mothers in Group 1 who were prescribed oxytocin nasal spray by the midwives was 86%. The study by [Kvist 2004](#) was discontinued prematurely because the authors felt it necessary to include cultivation of breast milk from all participants and follow-up of the mothers after six weeks.

Primary outcomes

Breast pain (as described by trial authors) (not prespecified)

Gua-Sha therapy may reduce breast pain more than hot packs with massage, according to pain measured by 0-10 VAS (MD -2.01, 95% CI -2.60 to -1.42; 54 women; [Analysis 6.1](#); [Summary of findings 6](#); low-certainty of evidence; [Chiu 2010](#)).

Breast induration/hardness (as described by trial authors) (not prespecified)

Not reported.

Breast swelling (as described by trial authors) (not prespecified)

Not reported.

Breast engorgement

Gua-Sha therapy may reduce breast engorgement (measured on a 0-10 visual analogue scale) compared with hot packs with massage (MD -2.42, 95% CI -2.98 to -1.86; 54 women; [Analysis 6.2](#); [Chiu 2010](#)). There may be little or no difference in the risk of breast engorgement between acupuncture and usual care (RR 0.72, 95% CI 0.47 to 1.10; 210 women; [Analysis 6.3](#); [Kvist 2007](#)). Another study found lower breast engorgement scores in women who had acupressure than those who had routine care but again the data were reported per breast ([Kamali Moradzade 2013](#); [Summary of findings 6](#); very low-certainty evidence).

Secondary outcomes

Pyrexia

One study reported a lower risk of pyrexia in the group that had acupuncture compared with the usual care group (RR 0.82, 95% CI 0.72 to 0.94; 210 women; [Analysis 6.5](#); [Kvist 2007](#)).

Mastitis

Not reported.

Breast abscess

One study reported breast abscess in 2/140 women in the group that had acupuncture and 5/70 in the usual care group (RR 0.20, 95% CI 0.04 to 1.01; 210 women; [Analysis 6.6](#); [Kvist 2007](#)).

Maternal opinion of treatment

Not reported.

Analgesic requirement

Not reported.

Hospital admission

Not reported.

Woman's confidence in continuing to breastfeed

In one study, there was little or no difference in the mothers' expression of **satisfaction with the breastfeeding experience** between the acupuncture group and usual care group ([Kvist 2007](#)).

Cessation of breastfeeding

It is uncertain if more women stop breastfeeding following treatment with acupuncture compared with usual care because the certainty of evidence is low and the CIs were wide, indicating that the true effect may be either appreciable harm or benefit (RR 0.50, 95% CI 0.17 to 1.49; 210 women; studies = 1) ([Summary of findings 6](#); [Analysis 6.4](#); [Kvist 2007](#)).

Number of women with adverse events

One study reported that women in the Gua-Sha group had "mild skin redness and elevation" but that the participants "did not report perceiving any discomfort in the treatment areas" ([Chiu 2010](#)). No other information was given about adverse events in the other studies.

Comparison seven: ultrasound treatment versus control treatment

One study ([McLachlan 1991](#)) examined ultrasound versus sham ultrasound in a study where breasts rather than women were randomised (women may have had active treatment on both breasts, sham treatment on both breasts, or one breast receiving active, and the other receiving sham ultrasound). No adjustment was made for the non-independence of breasts and the results were difficult to interpret. One study compared non-thermal therapeutic ultrasound to breastfeeding advice and breast massage ([Sankanagoudar 2011](#)) but the outcome data were reported in poor quality visual form that was impossible to read.

Primary outcomes

Neither of the two ultrasound studies reported useable data relating to our primary outcomes.

Secondary outcomes

Pyrexia

Not reported.

Mastitis

Not reported.

Breast abscess

Not reported.

Maternal opinion of treatment

Not reported.

Analgesic requirement

In one study ([McLachlan 1991](#)), 14/22 women who had ultrasound required analgesia, compared to 15/23 women who had sham ultrasound (RR 0.98, 95% CI 0.63 to 1.51; 45 women; [Analysis 7.1](#)).

DISCUSSION

Summary of main results

In this version of the review, 21 studies involving 2170 breastfeeding women were analysed. A range of interventions for the treatment of breast engorgement were tested. These included: cabbage leaves, various compresses (ginger, cactus/aloe, hollyhock), massage plus cactus and aloe compress, acupuncture, ultrasound, acupressure, scraping therapy (*Gua Sha*), cold breast-packs, electromechanical massage, Oketani breast massage, and medical treatments (serrapeptase, protease, oxytocin). Six studies used individual breasts as the unit of analysis making it difficult to evaluate the true effect of the studied intervention. Due to the heterogeneous interventions, we were unable to pool results in meta-analysis; hence, a qualitative analysis resulted in the following findings.

Cabbage leaf treatments compared to control

For breast pain, cold cabbage leaves may be more effective than routine care or cold gel packs but the evidence is very low certainty. In other studies, comparing cold cabbage leaves to room temperature cabbage leaves, room temperature cabbage leaves to hot water bag, and cabbage leaf extract cream to placebo cream, the confidence intervals were wide and included no effect, therefore we cannot be certain about the effect estimates.

For breast hardness, cold cabbage leaves may be more effective than routine care; whereas, in the same study, we are not certain if cold cabbage leaves have any effect compared to cold gel packs.

For breast engorgement, we are not certain if room temperature cabbage leaves may be more effective than a hot water bag or if cabbage leaf extract cream has any effect compared with placebo cream.

More women were satisfied with cold cabbage leaves than with routine care or with cold gel packs. There may be little difference in women's satisfaction comparing cold gel packs with routine care.

Breast swelling and number of women with adverse events were not reported. Overall, the body of evidence was judged to be of low-certainty due to risk of bias, low numbers of participants, and inconsistency in outcome effects.

Compress treatments compared to control

For breast pain, herbal compress may be more effective than hot compress. Massage therapy plus cactus and aloe compress may be more effective than massage therapy alone. In a comparison of cactus and aloe compress to massage therapy, the confidence intervals were wide and included no effect. Cactus and aloe cold compress may reduce the risk of breast hardness compared to massage. Massage plus cactus and aloe cold compress may reduce the risk of breast hardness even further compared to massage alone. We are uncertain about the effects of compress treatments on breast engorgement and cessation of breastfeeding because the certainty of evidence is very low. Among women receiving herbal compress treatment, 2/250 experienced skin irritation compared to none in the hot compress group (moderate-certainty evidence), but this adverse effect resolved within 24 hours, without any additional treatment. Breast swelling and maternal opinion of treatment were not reported. We judged the evidence relating to breast pain and breast hardness as low-certainty due to risk of bias.

Cold gel packs compared to control

For breast pain, we are uncertain about the effectiveness of cold gel packs compared to control treatments because the certainty of evidence is very low. We judged the evidence relating to breast hardness and cessation of breastfeeding as low-certainty. Cold gel packs may reduce breast hardness symptoms compared to routine care. It is uncertain if more women stop breastfeeding following cold gel pack treatment compared to routine care because the confidence intervals were wide and included no effect. Breast swelling, engorgement and number of women with adverse events were not reported.

Massage-based treatments compared to control

Adding massage therapy to cactus and aloe cold compress may be more effective than cactus and aloe cold compress alone for breast pain and breast hardness. It is uncertain if Oketani breast massage is more effective than routine care for breast engorgement. It is also uncertain if fewer women stop breastfeeding following treatment with massage plus cactus and aloe cold compress compared with cactus and aloe cold compress alone. The certainty of evidence is low due to risk of bias, small numbers of participants and reporting of data per breast instead of per woman. We found no evidence from this intervention relating to breast swelling, women's opinion of treatment or adverse events.

Medical treatments compared to placebo

In this category, we included studies looking at protease, serrapeptase and oxytocin. Protease may reduce the risk of breast pain and breast swelling, and serrapeptase may reduce the risk of breast engorgement compared to placebo. Women treated with protease complex were less likely to have no improvement in pain and swelling on the fourth day of treatment and less likely to experience no overall change in their symptoms or worsening of symptoms. It should be noted, though, that it is more than 40 years since the study was carried out, and we are not aware whether this preparation is used in current practice. We are uncertain if serrapeptase reduces breast pain or swelling compared to placebo, or if oxytocin reduces breast engorgement compared to placebo, because the confidence intervals were wide and included no effect. No women experienced adverse events in any of the groups receiving serrapeptase, protease or placebo (low-certainty evidence). Breast induration/hardness, maternal opinion of treatment and cessation of breast feeding were not reported. We judged the evidence relating to medical treatments as low-certainty due to risk of bias and low numbers of participants.

Ultrasound compared to sham ultrasound

We found no evidence relating to our primary outcomes from trials investigating ultrasound treatment.

Other therapies

In this category, we included studies looking at acupressure, acupuncture and scraping therapy. Gua-Sha therapy may be more effective than hot packs with massage for reducing breast pain.

For breast engorgement, we are uncertain about the effect of Gua-Sha therapy, acupuncture or acupressure because the certainty of evidence is very low.

In one study, slightly fewer women who had undergone acupuncture stopped breastfeeding compared to the usual care group, but the confidence intervals were wide and included no effect.

Breast induration/hardness, breast swelling, maternal opinion of treatment and adverse events were not reported. We judged the evidence as low-certainty due to risk of bias, small number of participants, and reporting of some data per breast instead of per woman.

For several interventions with sham or placebo comparisons (ultrasound, cabbage leaf extract cream, and subcutaneous oxytocin), women tended to have improvements in pain and other symptoms over time whether or not they received active treatment. The improvement in symptoms may be partly explained by the placebo effect, or it may be due to the fact that symptoms resolved spontaneously as women continued to breastfeed. Given that milk stasis is thought to be the main cause of breast engorgement, regular, responsive breastfeeding should be encouraged.

Overall completeness and applicability of evidence

The studies included in this review were conducted in a variety of countries (Australia, Brazil, China, India, Iran, Japan, Singapore, Sweden, Taiwan, Thailand, USA) enabling applicability to a wide range of settings.

Little information was provided on what women thought of particular interventions; cold packs, for example, may be soothing for some women or may be uncomfortable for others; trials included in the review did not tend to report what women's views and preferences regarding treatment options were, apart from one study (Roberts 1995a) in which two-thirds of women stated that they preferred cabbage leaves to gel packs, with some mothers volunteering the information that cabbage leaves gave a stronger, more immediate effect, while others felt that chilled gel packs gave a more lasting effect in the treatment of breast engorgement.

We found four ongoing studies investigating other interventions for the treatment of breast engorgement, therefore this body of evidence will continue to grow. However, these ongoing studies are unlikely to strengthen the certainty of the evidence we have identified because the numbers of women participating will be relatively low and the interventions are heterogeneous.

Furthermore, definitions of engorgement used in the studies varied, complicating matters further. Some studies included women with a broad range of symptoms described as "inflammatory processes of the breast" (Kvist 2004; Kvist 2007), such as erythema, tension, pain and pyrexia, whereas others only included lactating women with "breast hyperaemia" (Kamali Moradzade 2013). In one study (Chiu 2010), engorgement is defined as "swelling and distension of the breasts", whereas in another it is defined as "puerperal milk stasis". Efforts to better define engorgement, as well as agree upon standard outcomes and measuring tools used, would greatly improve the completeness and applicability of evidence.

Quality of the evidence

Despite the contributions made by the authors and study participants in the 21 studies included in this review, we found the evidence for most outcomes to be at high risk of bias due to the small sample sizes in most studies (imprecision), inadequate sequence generation and allocation concealment (selection bias), lack of blinding of women, staff and outcome assessors (performance bias and detection bias), and potential conflict of interest, with three studies (Kee 1989; Murata 1965; Roberts 1998) receiving funding from industry. Of note is that two-thirds of author teams did not make a declaration of potential conflicts of interest.

The lack of blinding in studies may mean that evidence regarding symptoms (reported by women or assessed by clinicians) may be at high risk of bias. Even though blinding of women and clinicians cannot always be conducted, where a placebo is not available, blinding of outcome assessors should be ensured to keep detection bias to a minimum. Most of the studies did not have sufficient statistical power to detect differences between groups and so results are not conclusive, and while outcomes that occur relatively infrequently were not generally reported, it is unlikely that these studies would have been large enough to show possible differences. The studies also had relatively short follow-up periods (as outcomes such as symptom improvement are apparent within a few days), which meant that information on longer-term outcomes such as incidence of mastitis or abscess formation, or breastfeeding cessation were not available. Randomisation of breasts in some studies may mean that results are at high risk of bias as breasts are not independent; asking mothers who are not blinded to breast assignments to rate individual breasts (when at pre-test they provided a single rating for both breasts) may lead to findings that

are at best, difficult to interpret, and at worst, not valid. Finally, in one study (Robson 1990), the randomisation procedure was not adhered to; women with the most distressing symptoms assigned to the control group were moved into the intervention group, defeating the purpose of randomisation.

Overall, the certainty of evidence is low or very low. We downgraded the evidence presented in the 'Summary of Findings' tables for several reasons. We judged the risk of bias, as discussed above, to be serious enough to downgrade one level. Additionally, we downgraded for imprecision due to the small numbers of women participating in the studies. Finally, we downgraded the evidence from studies where analysis was per breast for serious indirectness.

Potential biases in the review process

All available randomised and quasi-randomised controlled trials investigating the treatment of breast engorgement in breastfeeding women were included in this review, with no language restrictions. We attempted to be as inclusive as possible by going to great lengths to contact authors of reports requesting clarification of methodology or results.

We acknowledge that there is potential for bias in the review process as assessment of risk of bias, for example, is not an exact science and is subject to individual interpretation. We attempted to minimise this by: 1) having two review authors independently assess risk of bias and carry out data extraction; and 2) contacting study authors to clarify study methods.

Primary outcomes studied in this review were not prespecified in the protocol. These outcomes were added for the 2016 update because it was felt that more patient-important outcomes, directly related to the studied condition, were needed. This is unlikely to have introduced bias to the review.

Agreements and disagreements with other studies or reviews

Clinical practice guidelines in the UK (NICE 2006) broadly agree with this review concluding that cabbage leaves and cold packs may be helpful for symptom relief, but that evidence on the effectiveness of these interventions is not strong.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence from trials to support the widespread implementation of a particular treatment for breast engorgement. At the same time, treatments such as cold packs, massage, herbal compresses or cabbage leaves applied to the breast may be soothing, are unlikely to be harmful, are inexpensive and readily available.

Implications for research

Encouragingly, a dozen clinical trials on the treatment of breast engorgement have been registered since the publication of the 2016 Cochrane update, suggesting increasing interest in this topic and potentially useful studies for future updates of this review. If clinical trials are to provide useful evidence, it is essential that researchers adhere to recommended guidelines (e.g. CONSORT) for the conduct and reporting of studies. Low-risk methods of sequence generation should be used and concealment of

participant allocation needs to be ensured. These important steps should be described in sufficient detail in published protocols as well as in trial reports. Studies where individual breasts have been randomised are particularly difficult to interpret due to the unreliability of the results; hence, this study design should be avoided in future research. Overcoming problems associated with lack of blinding and subsequent placebo effect is a particular challenge in this area. Comparing alternative treatment options using a cluster-randomised design rather than randomising individual women may be a possible way forward to ensure bigger numbers and to avoid contamination. In cases where cluster-randomised trials are not feasible, using an objective instrument for measuring breast engorgement, such as tonometry for measuring breast induration/hardness, may be a solution. At the same time, studies should also measure patient-important outcomes, such as breast pain, cessation of breastfeeding, maternal opinion of treatment and adverse events. In addition, cost-effectiveness of tested interventions needs to be addressed. Whenever possible, outcome assessors should be blinded to group allocation. Future trials should focus on the above mentioned potentially effective interventions to enable meta-analysis of similar studies, rather than explore new treatments, hence increasing the heterogeneity of interventions with limited evidence. Further research into the active ingredient of cabbage leaves may be warranted, as well as the comparison of cold versus warm packs pre- and post-feeds. Finally, more basic research is needed on the physiology of breast engorgement during lactation to aid understanding of mechanisms underpinning treatment options.

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REFERENCES

References to studies included in this review

Batista 2014 {published data only}

Batista dos Santos HA, Muniz de Moura MA, De Souza MA, Nohama P. Evaluation of massage techniques and pumping in the treatment of breast engorgement by thermography [Evaluacion de las tecnicas de masaje y bombeo en el tratamiento de la congestión mamaria por termografía]. *Revista Latino-Americana de Enfermagem (RLAE)* 2014;**22**(2):277-85.

Chiu 2010 {published data only}

Chiu JY, Gau ML, Kuo SY, Chang YH, Kuo SC, Tu HC. Effects of Gua-Sha therapy on breast engorgement: a randomized controlled trial. *Journal of Nursing Research* 2010;**18**(1):1-10.

Dehghani 2017 {published data only}

Dehghani M, Babazadeh R, Khadivzadeh T, Pourhoseini SA, Esmaeili H. Effect of breast oketani-massage on neonatal weight gain: a randomized controlled clinical trial. *Evidence Based Care Journal* 2018;**8**(3):57-63.

* Dehghani M, Babazadeh R, Khadivzadeh T, Pourhoseini SA, Esmaeili H. Effect of breast oketani-massage on the severity of breast engorgement. *Iranian Journal of Obstetrics, Gynecology and Infertility* 2017;**20**(5):30-8.

IRCT2016062728669N1. The effect of breast oketani massage on breast engorgement and neonate weight gain. en.irct.ir/trial/23201 (first received 8 September 2016).

Ingelman-Sundberg 1953 {published data only}

Ingelman-Sundberg A. Early puerperal breast engorgement. *Acta Paediatrica Scandinavica* 1953;**32**:399-402.

Kamali Moradzade 2013 {published data only}

IRCT201204065698N3. The comparison of acupressure (jianjing point) and compress (hot and cold) on breast engorgement in lactating women. irct.ir/trial/6220 (first received 6 June 2012).

* Kamali Moradzade M, Ahmadi M, Heshmat R, Akbarzade Baghban AR. Comparing the effect of acupressure and intermittent compress on the severity of breast hyperemia in lactating women. *Quarterly of the Horizon of Medical Sciences* 2013;**18**(4):155-60.

Kee 1989 {published data only}

* Kee WH, Tan SL, Lee V, Samon YM. The treatment of breast engorgement with serrapeptase (Danzen): a randomized double-blind controlled trial. *Singapore Medical Journal* 1989;**30**(1):48-54.

Tan SL, Kee WH, Lee V, Salmon YM. The use of serratiopeptidase (Danzen) for the treatment of breast engorgement - a randomised double-blind controlled trial. In: 24th British Congress of Obstetrics and Gynaecology; 1986 April 15-18; Cardiff, UK. 1986:246.

Ketsuwan 2018 {published data only}

* Ketsuwan S, Baiya N, Paritakul P, Laosooksathit W, Puapornpong P. Effect of herbal compresses for maternal breast

engorgement at postpartum: a randomized controlled trial. *Breastfeeding Medicine* 2018;**13**(5):361-5.

TCTR20180208002. Effect of herbal compress on maternal breast engorgement at postpartum, a randomized controlled trial. www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialsearch&smenu=fulltext&task=search&task2=view18 (first received 8 February 2018).

Khosravan 2017 {published data only}

IRCT2014051917754N1. The effects of *Althaea officinalis* L leaf compress accompanied by cold & hot compresses on breast engorgement among lactating women: a randomized clinical trial. irct.ir/trial/16244 (first received 14 July 2014).

Khosravan S, Moghadam HM, Mohammadzade F, Gholami M, Fadafen SAK. Effects of hollyhock leaves compress with cold and hot compress on breast congestion in lactating women. *Avicenna Journal of Phytomedicine* 2015;**5**(Suppl 1):6-7.

* Khosravan S, Mohammadzadeh-Moghadam H, Mohammadzadeh F, Fadafen SA, Gholami M. The effect of hollyhock (*Althaea officinalis* L) leaf compresses combined with warm and cold compress on breast engorgement in lactating women: a randomized clinical trial. *Journal of Evidence-Based Complementary & Alternative Medicine* 2017;**22**(1):25-30.

Kumari 2019 {published data only}

Kumari R. Effectiveness of green cabbage leaves (GCL) vs hot water bag (HWB) application on breast engorgement in postnatal mothers. *International Journal of Nursing Education* 2019;**11**(3):39-44.

Kvist 2004 {published data only}

Kvist LJ, Wilde Larsson B, Hall-Lord ML, Rydhstroem H. Effects of acupuncture and care interventions on the outcome of inflammatory symptoms of the breast in lactating women. *International Nursing Review* 2004;**51**(1):56-64.

Kvist 2007 {published data only}

Kvist LJ, Hall-Lord ML, Rydhstroem H, Larsson BW. A randomised-controlled trial in Sweden of acupuncture and care interventions for the relief of inflammatory symptoms of the breast during lactation. *Midwifery* 2007;**23**:184-95.

McLachlan 1991 {published data only}

* McLachlan Z, Milne EJ, Lumley J, Walker BL. Ultrasound treatment for breast engorgement: a randomised double blind trial. *Australian Journal of Physiotherapy* 1991;**37**(1):23-9.

McLachlan Z, Milne EJ, Lumley J, Walker BL. Ultrasound treatment for breast engorgement: a randomised double blind trial. *Breastfeeding Review* 1993;**2**(7):316-20.

McLachlan Z, Milne J, Lumley J. The efficacy of ultrasound as a treatment for severe breast engorgement. In: Tenth International Congress World Confederation for Physical Therapy; 1987 May 17-22; Sydney, Australia. 1987:342-6.

Meng 2015 {published data only}

Meng S, Deng Q, Feng C, Pan Y, Chang Q. Effects of massage treatment combined with topical cactus and aloe on puerperal milk stasis. *Breast Disease* 2015;**35**(3):173-8.

Monazzami 2019 {published data only}

IRCT20180508039585N1. The effect of ginger compress on breast engorgement in lactating women. irct.ir/trial/31056 (first received 15 May 2018).

* Monazzami M, Yousefzadah S, Rakhshandeh H, Esmaeili H, Afiat M. The effect of hot ginger compress (zingiber officinale) on the severity of breast engorgement in lactating women. *Iranian Journal of Obstetrics, Gynecology and Infertility* 2019;**21**(12):77-84.

Murata 1965 {published data only}

Murata T, Hanzawa M, Nomura Y. The clinical effects of "Protease complex" on postpartum breast engorgement (based on the double blind method). *Journal of Japanese Obstetrical and Gynecological Society* 1965;**12**(3):139-47.

Roberts 1995a {published data only}

Roberts KL. A comparison of chilled cabbage leaves and chilled gelpaks in reducing breast engorgement. *Journal of Human Lactation* 1995;**11**(1):17-20.

Roberts 1995b {published data only}

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**:191-4.

Roberts 1998 {published data only}

Roberts KL, Reiter M, Schuster D. Effects of cabbage leaf extract on breast engorgement. *Journal of Human Lactation* 1998;**14**(3):231-6.

Robson 1990 {published data only}

Robson BA. Breast Engorgement in Breastfeeding Mothers [thesis]. Case Western Reserve University, 1990.

Sankanagoudar 2011 {published data only}

Sankanagoudar PP, Patil C, Singed K. Effect of therapeutic non-thermal ultrasound on post-partum symptomatic breast engorgement. *Indian Journal of Physiotherapy & Occupational Therapy* 2011;**5**(2):108-13.

Wong 2017 {published data only}

Wong BB, Chan YH, Leow MQH, Lu Y, Chong YS, Koh SSL, et al. Application of cabbage leaves compared to gel packs for mothers with breast engorgement: randomised controlled trial. *International Journal of Nursing Studies* 2017;**76**:92-9.

References to studies excluded from this review
Booker 1970 {published data only}

Booker DE, Pahl IR, Forbes DA. Control of postpartum breast engorgement with oral contraceptives II. *American Journal of Obstetrics and Gynecology* 1970;**108**:240-2.

Filteau 1999 {published data only}

Filteau SM, Lietz G, Mulokozi G, Bilotta S, Henry CJ, Tomkins AM. Milk cytokines and subclinical breast inflammation in Tanzanian women: effects of dietary red palm oil or sunflower oil supplementation. *Immunology* 1999;**97**:595-600.

Gao 2018 {published data only}

* Gao H, Ma X, He X, Guo Y, Ding S, Yun Z, et al. Clinical study on ductal probing in treating milk stasis. *Chinese Journal of Breast Disease* 2018;**12**(3):155-9. [CENTRAL: CN-02054319]

Gao H, Wang J. Study on the ductal probing of treating the milk stasis. *Breastfeeding Medicine* 2016;**11**(Suppl 1):S-12. [CENTRAL: CN-02054320]

Garry 1956 {published data only}

Garry J. Estrogen-androgen preparation for prevention of postpartum breast engorgement and lactation. *Obstetrics & Gynecology* 1956;**7**:422-4.

KCT0002436 {published data only}

KCT0002436. Randomised controlled trials of myofascial release massage on breastfeeding mothers' pectoralis major muscle for breast pain and engorgement and newborns' breast milk intake and sleeping time. cris.nih.go.kr/cris/en/search/search_result_st01.jsp?seq=8262 (first received 1 September 2017).

King 1958 {published data only}

King AG. Prevention of puerperal breast engorgement with large doses of long-acting estrogen. *American Journal of Obstetrics and Gynecology* 1958;**78**:80-5.

NCT032307602017 {published data only}

NCT03230760. Acupuncture for breast engorgement during lactation: a pilot study. clinicaltrials.gov/ct2/show/NCT03230760 (first received 26 July 2017).

Nikodem 1993 {published data only}

Danziger D, Gebka N, Nikodem C, Gulmezoglu M, Hofmeyr GJ. Do cabbage leaves prevent breast engorgement? Randomised, controlled study. In: 12th Conference on Priorities in Perinatal Care; 1993; South Africa. 1993:114-6.

* Nikodem VC, Danziger D, Gebka N, Gulmezoglu AM, Hofmeyr GJ. Do cabbage leaves prevent breast engorgement? a randomized, controlled study. *Birth* 1993;**20**(2):61-4.

Phillips 1975 {published data only}

Phillips WP. Prevention of postpartum breast engorgement: double-blind comparison of chlorotrianisene 72 mg and placebo. *Journal of the Arkansas Medical Society* 1975;**72**:163-7.

Roser 1966 {published data only}

Roser DM. Breast engorgement and postpartum fever. *Obstetrics & Gynecology* 1966;**27**:73-7.

Ryan 1962 {published data only}

Ryan GM Jr, Brown DAJ. Intranasal syntocinon and postpartum breast engorgement. *Obstetrics & Gynecology* 1962;**20**:582-4.

Stenchever 1962 {published data only}

Stenchever MA. Evaluation of chlorprophenpyridamine for prevention of postpartum breast engorgement. *American Journal of Obstetrics and Gynecology* 1962;**84**:969-71.

References to ongoing studies

IRCT2017062633812N2 {published data only}

IRCT2017062633812N2. Investigating the effect of Commiphora mukul cream on improvement of breast engorgement of women referred to the health center of Kerman University of Medical Science in 2015-2016. //irct.ir/trial/25990 (first received 19 July 2017).

IRCT20190608043838N1 {published data only}

IRCT20190608043838N1. The effect of foot reflexology on the breast engorgement lactating mothers. //irct.ir/trial/40071 (first received 19 June 2019).

NCT03985579 {published data only}

NCT03985579. Influence of kinesiology taping application on severity of signs and symptoms in breast engorgement. //clinicaltrials.gov/ct2/show/NCT03985579 (first received 13 June 2019).

TCTR20181123001 {published data only}

TCTR20181123001. Continuous ultrasound diathermy combined with conventional therapies versus conventional therapies alone for breast engorgement in postpartum lactating women: a randomized controlled study. www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialsearch&smenu=fulltext&task=search&task2=view18&id=4154 (first received 8 November 2018).

Additional references

ABM 2016

Berens P, Brodribb W. ABM Clinical Protocol #20: Engorgement, Revised 2016. *Breastfeeding Medicine* 2016;**11**(4):159-63.

Acarturk 2005

Acarturk S, Gensel E, Tuncer I. An uncommon complication of secondary augmentation mammoplasty: bilaterally massive engorgement of breasts after pregnancy attributable to postinfection and blockage of mammary ducts. *Aesthetic Plastic Surgery* 2005;**29**(4):274-9.

Carletti 2011

Carletti C, Pani P, Knowles A, Monasta L, Montico M, Cattaneo A. Breastfeeding to 24 months of age in the northeast of Italy: a cohort study. *Breastfeeding Medicine* 2011;**6**(4):177-82.

Core Curriculum 2013

Mannel R, Martens PJ, Walker M. Core Curriculum for Lactation Consultant Practice. 3rd edition. Burlington: Jones & Bartlett Learning, 2013.

Cotterman 2004

Cotterman KJ. Reverse pressure softening: a simple tool to prepare areola for easier latching during engorgement. *Journal of Human Lactation* 2004;**20**(2):227-37.

Foda 2004

Foda MI, Kawashima T, Nakamura S, Kobayashi M, Oku T. Composition of milk obtained from unmassaged versus massaged breasts of lactating mothers. *Journal of Pediatric Gastroenterology and Nutrition* 2004;**38**:484-7.

Giugliani 2004

Giugliani ER. Common problems during lactation and their management. *Jornal de Pediatria* 2004;**80**(5 Suppl):S147-54.

Hale 2007

Hale TW, Hartmann PE. Chapter 7: Hormonal control of the lactation cycle. In: Textbook of Human Lactation. 1st edition. Amarillo: Hale Publishing, 2007.

Hauck 2011

Hauck YL, Fenwick J, Dhaliwal SS, Butt J. A Western Australian survey of breastfeeding initiation, prevalence and early cessation patterns. *Maternal Child Health Journal* 2011;**15**(2):260-8.

Higgins 2019

Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 6 (updated July 2019). Cochrane 2019. www.training.cochrane.org/handbook.

Hill 1994

Hill PD, Humenick SS. The occurrence of breast engorgement. *Journal of Human Lactation* 1994;**10**(2):79-86.

Humenick 1994

Humenick SS, Hill PD, Anderson MA. Breast engorgement: patterns and selected outcomes. *Journal of Human Lactation* 1994;**10**(2):87-93.

Hure 2013

Hure AJ, Powers JR, Chojenta CL, Byles JE, Loxton D. Poor adherence to national and international breastfeeding duration targets in an Australian longitudinal cohort. *PLOS One* 2013;**8**(1):e54409.

Lauche 2016

Lauche R, Gräf N, Cramer H, Al-Abtah J, Dobos G, Saha FJ. Efficacy of cabbage leaf wraps in the treatment of symptomatic osteoarthritis of the knee. *Clinical Journal of Pain* 2016;**11**:961-71.

Liu 2013

Liu P, Qiao L, Xu F, Zhang M, Wang Y, Binns C. Factors associated with breastfeeding duration: a 30-month cohort study in northwest China. *Journal of Human Lactation* 2013;**29**(2):253-9.

Mass 2004

Mass M. Breast pain: engorgement, nipple pain and mastitis. *Clinical Obstetrics and Gynecology* 2004;**47**(3):676-82.

NICE 2006

Demott K, Bick D, Norman R, Ritchie G, Turnbull N, Adams C, et al. Clinical Guidelines and Evidence Review for Postnatal Care: Routine Postnatal Care of Recently Delivered Women and Their Babies. London: National Collaborating Centre For Primary Care And Royal College Of General Practitioners, 2006.

Odom 2013

Odom EC, Li R, Scanlon KS, Perrine CG, Grummer-Strawn L. Reasons for earlier than desired cessation of breastfeeding. *Pediatrics* 2013;**131**(3):e726-32.

RevMan 2014 [Computer program]

Nordic Cochrane Centre, The Cochrane Collaboration Review Manager 5 (RevMan 5). Version 5.3. Copenhagen: Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

WHO 2003

World Health Organization. Global Strategy for Infant and Young Child Feeding. Geneva: WHO, 2003.

References to other published versions of this review

Mangesi 2010

Mangesi L, Dowswell T. Treatments for breast engorgement during lactation. *Cochrane Database of Systematic Reviews* 2010, Issue 9. Art. No: CD006946. [DOI: [10.1002/14651858.CD006946.pub2](https://doi.org/10.1002/14651858.CD006946.pub2)]

Mangesi 2016

Mangesi L, Zakarija-Grkovic I. Treatments for breast engorgement during lactation. *Cochrane Database of Systematic Reviews* 2016, Issue 6. Art. No: CD006946. [DOI: [10.1002/14651858.CD006946.pub3](https://doi.org/10.1002/14651858.CD006946.pub3)]

Snowden 2001

Snowden HHM, Renfrew MJ, Woolridge M. Treatments for breast engorgement during lactation. *Cochrane Database of Systematic Reviews* 2001, Issue 2. Art. No: CD000046. [DOI: [10.1002/14651858.CD000046.pub2](https://doi.org/10.1002/14651858.CD000046.pub2)]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Batista 2014

Study characteristics

Methods	Quasi-randomised controlled trial. Single-centre study
Participants	<p>No. of participants: 16 women who sought care for engorgement</p> <p>Setting: Human Milk Bank, Hospital Universitario Evangelico de Curitiba, Curitiba, Brazil</p> <p>Inclusion criteria: women aged 18 or over who were between 3 and 10 days postpartum with moderate and/or intense bilateral engorgement, regardless of location in the breast</p> <p>Exclusion criteria: women with a history of mammoplasty and/or breast prosthesis; use of synthetic oxytocin; use of analgesics in the 6 hours prior to the study; use of cream or talc on the breasts on the exam day; having had a bath up until an hour before the study; exposure to sunlight or light in the 2 hours before the study; history of a palpable or non-palpable breast lesion; previous history of lactational mastitis; obstructive glandular engorgement; tissue integrity impaired in any region of the breast; unwilling to participate</p>
Interventions	<p>Intervention group (n = 8): 1 min of electromechanical breast massage followed by mechanical pumping, if softening of the breast occurred. If no softening occurred following initial massage, then massager applied for a further 2 min before pumping. A domestically manufactured, vibro-therapeutic massager under the trademark 'Physical' was used; whereas for milk expression a 'Medela' pump in high vibration mode, at maximum suction, was applied.</p> <p>Control group (n = 8): 1 min of manual breast massage followed by manual pumping, if softening occurred. If no softening occurred following initial massage, then a further 2 min of manual massage was performed prior to pumping.</p> <p>No information was provided on the massage technique used nor on the duration of pumping (milk expression).</p> <p>Duration of treatment: up to 3 mins of massage time plus pumping time</p>

Batista 2014 (Continued)

Duration of follow-up: 15 mins after pumping session

Adverse events: not reported

Outcomes	Temperature of the breasts measured, using thermography, 15 mins after intervention
Notes	<p>Dates of study: 24th January- 23rd February, 2011</p> <p>Funding sources: no funding received</p> <p>Declarations of interest: "No conflicts of interest"</p> <p>Corresponding author contacted 20.11.2019 and 16.12.2019; response received 16.12.2019: funding sources and potential interests clarified</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"The investigator flipped a coin. With the result "face", the first lactating woman would be in the control group...If it was crown, the lactating woman belonged to the experimental group...Thus the two methods of treatment were alternated starting from the initial random selection."
Allocation concealment (selection bias)	High risk	"The two methods of treatment were alternated."
Blinding of participants and personnel (performance bias) All outcomes	High risk	The types of interventions did not allow blinding of women or clinicians.
Blinding of outcome assessment (detection bias)	Unclear risk	Blinding of outcome assessors was not mentioned and it was not clear whether the outcome assessor was independent of the clinician performing the intervention.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	A sample size of 196 women was calculated but only 16 were in the final sample. According to the authors, the "sample was compromised due to the lack of availability of the instrumentation, the acclimatization period required for application of the thermography protocol, and the lack of signed consent forms". It was unclear whether women dropped out before or after study inclusion, and if afterwards, how many belonged to each group.
Selective reporting (reporting bias)	High risk	"In the evaluation, two methods were applied: clinical exam and thermographic exam..." but only breast temperature was reported pre-and post-intervention. According to the authors, the degree of breast swelling, breast tenderness and intensity of engorgement symptoms were measured pre-intervention but they were not reported in the article. It was unclear whether the measurements were repeated post-intervention. The latter outcomes would have been more useful for assessing the effectiveness of the intervention, as they are common symptoms of breast engorgement.
Other bias	High risk	<p>Varying degrees of engorgement among women prior to treatment were alluded to but no data specifically given for study groups.</p> <p>A sample size of 196 women was calculated as being necessary but only 16 were in the final sample suggesting that the study was severely underpowered.</p>

Chiu 2010

Study characteristics

Methods	Randomised controlled trial. Single-centre study
Participants	<p>No. of participants: 60 breastfeeding women</p> <p>Setting: medical centre, centralTaiwan.</p> <p>Inclusion criteria: a) breast engorgement (diagnosed as having hot, painful, hard breasts; non-flow of milk; abnormal thirst levels; and breast tenderness); b) no high-risk complications both before or following childbirth ("high risk" not defined); and c) willingness to participate</p>
Interventions	<p>Intervention group (n = 27): short and soft <i>Gua-Sha</i> scraping therapy was applied to acupoints ST16, ST18 and SP17, in the direction of the nipples. In addition, scraping therapy was applied between the engorged breasts to acupoints CV17. Each position was lightly scraped 7 times in 2 cycles before the next breastfeed. Intervention time was 2 +/- 0.5 min.</p> <p>Control group (n = 27): small towels were immersed in hot water, of $43 \pm 2^\circ\text{C}$, and then applied to the breasts. This was followed by massage, done using the index and middle fingers in a spiral motion towards the nipples. Intervention time in the control group was 20 ± 2 min.</p> <p>Duration of treatment: 2-20 min</p> <p>Duration of follow-up: 30 min</p> <p>Adverse events: "The force delivered in the therapy ...resulted in mild skin redness and elevation. Participants did not report perceiving any discomfort in the treatment areas."</p>
Outcomes	Breast engorgement symptoms based on Severity of Breast Engorgement Scale (SBES) measured at 5 min and 30 min post-treatment. SBES addresses pain, engorgement and discomfort, measured with a VAS (0 to 10). Breast and body temperatures (measured with digital infrared thermal imaging system) and vital signs (BP) were recorded at 5 min and 30 min post-treatment.
Notes	<p>The standard deviation of changes from baseline was missing for all variables so we used a correlation coefficient of 0.80 to impute the change-from-baseline standard deviation according to the formula provided in the <i>Cochrane Handbook for Systematic Reviews of Interventions</i> (Ch. 16.1.3.2).</p> <p>Dates of study: June 10, 2005 to April 4, 2006</p> <p>Funding sources: "No funding"</p> <p>Declarations of interest: "No conflict of interest"</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computer-generated block randomisation list."
Allocation concealment (selection bias)	Unclear risk	Not reported. Author contacted, additional information not provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>"Open trial, i.e. all participants knew to which group they had been assigned."</p> <p>"Open trial"; "the primary investigator handled all interventions."</p>

Chiu 2010 (Continued)

Blinding of outcome assessment (detection bias)	Low risk	"All data were collected by a nurse who was blinded to patient group assignments."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Author contacted to clarify inclusions/exclusions: 60 participants initially recruited of which 30 were in the experimental group and 30 in the control group. 6 women were "removed" from the study due to: fever (n = 2), early discharge (n = 2) and fatigue (n = 2). Final number of participants: 54 (27 in each group). Hence, attrition appeared balanced in number and reason across groups.
Selective reporting (reporting bias)	Low risk	BP results not reported, but least relevant to study objectives
Other bias	Low risk	"The groups showed no statistically significant differences in any variables except for age. No significant differences were found between groups in terms of pretest variables."

Dehghani 2017

Study characteristics

Methods	Randomised clinical trial. Multicentre study
Participants	<p>No. of participants: 100 breastfeeding women with breast engorgement</p> <p>Setting: women were recruited from 2 health centres and 2 hospitals in Mashhad, Iran.</p> <p>Inclusion criteria (mother): breast engorgement during first 5 days postpartum, minimum score of 2 out of 19 for severity of breast engorgement, willingness to participate in the study, not on medication which suppresses breastfeeding, no mastitis, T < 38°C, no contraindications to breastfeeding, currently breastfeeding, no history of breast surgery, did not have a high risk pregnancy or complicated delivery</p> <p>Inclusion criteria (infants): birthweight 2500-4000 g, no contraindications to breastfeeding, gestational age 37-42 weeks</p> <p>Exclusion criteria: T > 38°C during intervention, use of or need for any anti-inflammatory drugs during the intervention, not satisfied with being involved in the study, conducts the intervention only once, intervention interval for Oketani massage > 48 h, mastitis during intervention, neonatal complications such as fever or supplemental feeding (other than breastfeeding)</p>
Interventions	<p>Intervention group (n = 48): Oketani breast massage applied to both breasts for 30 min, once a day, for 2 consecutive days, + routine care</p> <p>Control group (n = 46): routine care (education on proper breastfeeding techniques, frequent breastfeeding, and hot compress)</p> <p>Duration of treatment: 30 min daily for 2 consecutive days</p> <p>Duration of follow-up: as above</p> <p>Adverse events: not reported</p>
Outcomes	Breast engorgement scores (reported per breast, not per woman)
Notes	<p>Dates of study: August 2016 (recruitment started); completion date not reported but, based on protocol registry, it was supposed to finish in 4 months.</p> <p>Funding sources: Mashhad University of Medical Sciences</p>

Dehghani 2017 (Continued)

Declarations of interest: none reported

Report kindly translated by members of Cochrane Iran

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"The eligible mothers were randomly assigned into two groups after delivery based on simple random sampling."
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not addressed in the report.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding was not addressed in the report. Given the nature of the intervention, blinding was unlikely.
Blinding of outcome assessment (detection bias)	High risk	Blinding was not addressed in the report. Given the nature of the intervention, blinding was unlikely.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition (n = 6): intervention group 2, control group 4; reasons not given
Selective reporting (reporting bias)	Low risk	There was consistency between the protocol (IRCT2016062728669N1) and the report.
Other bias	High risk	The data were analysed at the breast level with no adjustment for the non-independence of breasts. As mentioned in McLachlan 1991 , when the VAS was used, it was not always easy for women to make a clear distinction between the left and right breast.

Ingelman-Sundberg 1953

Study characteristics

Methods	Quasi-randomised trial. Allocation by folder numbers. Single-centre study
Participants	<p>No. of participants: 45 women</p> <p>Setting: women were located in a private hospital ward in Stockholm, Sweden.</p> <p>Inclusion criteria: "women who showed pronounced signs of engorgement", 2nd to 5th day postpartum</p>
Interventions	<p>Intervention group (n = 20): oxytocin 2.5 IU given subcutaneously daily to women until breasts became soft</p> <p>Control group (n = 25): a corresponding amount of physiological saline was given similarly.</p> <p>In both groups, the baby was allowed to breastfeed from the first day after delivery.</p> <p>Duration of treatment: "until breasts became soft"</p> <p>Duration of follow-up: 7 days</p>

Ingelman-Sundberg 1953 (Continued)

Adverse events: not reported

Outcomes	Amount of breast milk produced Duration of treatment before the engorgement disappeared
Notes	There were only limited data we were able to use in data tables. The authors stated that the baby was allowed to suckle from the first day after delivery and the volume of milk was measured. The results stated that the daily amount of milk produced was the same in both groups, although it was not clear how the amount of milk produced was measured. Dates of study: 1951-1952 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Odd or even folder numbers
Allocation concealment (selection bias)	High risk	There was no allocation concealment. Women were allocated into different groups based on their hospital records.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"It was concealed from both patient and doctor whether oxytocin or saline was being used."
Blinding of outcome assessment (detection bias)	Unclear risk	The article did not mention blinding of outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The study did not mention how incomplete outcome data were addressed.
Selective reporting (reporting bias)	Unclear risk	The authors reported their outcomes in percentages not in numbers out of the totals; which made it difficult to determine the denominators.
Other bias	Low risk	No other bias identified

Kamali Moradzade 2013
Study characteristics

Methods	Randomised controlled trial. Single-centre study
Participants	No. of participants: 70 "lactating women with breast engorgement" Setting: Gha'em Hospital, Fars, Iran Exclusion criteria: mothers with a breast abscess, fever (defined as T > 38°C), sore/cracked nipples, heart disease, shoulder injury, history of breast surgery, use of traditional herbal remedies for breast engorgement and mothers who did not want to take part in the study

Treatments for breast engorgement during lactation (Review)

Kamali Moradzade 2013 (Continued)

Interventions	<p>Intervention group (n = 35): acupressure, using hand massage, was applied simultaneously to both breasts for 2 min, followed by a 30-second rest. This was repeated for a total of 20 min and performed twice a day, on 2 consecutive days (a total of 4 times over 2 days).</p> <p>Control group (n = 35): hot (43-46°C) and cold (10-18° C) compresses were applied intermittently (2 min each) to both breasts simultaneously for 20 min, twice a day, on 2 consecutive days (a total of 4 times over 2 days)</p> <p>Duration of treatment: 20 min, twice a day, for 2 days</p> <p>Duration of follow-up: 2 days</p> <p>Adverse events: not reported</p>	
Outcomes	Breast engorgement severity index based on degree of breast tension, erythema and pain	
Notes	<p>The study used individual breasts as the unit of analysis.</p> <p>Dates of study: March 2009 - August 2010</p> <p>Funding sources: Shahid Beheshti University Of Medical Science</p> <p>Declarations of interest: not reported</p> <p>Corresponding author contacted 20.11.2019 to clarify RoB and DoI - invalid email</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The paper stated that the 70 women were only randomly assigned to 1 intervention or the other in a way that would create 2 intervention groups of 35 each but the method of sequence generation was not specified.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The type of intervention did not allow blinding of women or clinical staff.
Blinding of outcome assessment (detection bias)	High risk	The outcome assessor based results on a "breast engorgement checklist", but no blinding was done.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data - all patients were followed up.
Selective reporting (reporting bias)	Low risk	The results were strictly based on the authors' pre-made checklist.
Other bias	High risk	The data were analysed at the breast level with no adjustment for the non-independence of breasts. As mentioned in McLachlan 1991 , when the VAS was used, it was not always easy for women to make a clear distinction between the left and right breast.

Kee 1989

Study characteristics

Methods	Double-blind randomised controlled trial. Single-centre study
Participants	<p>No. of participants: 70 women</p> <p>Setting: postpartum hospital ward in urban Singapore</p> <p>Inclusion criteria: postpartum women with breast engorgement. Diagnosis of breast engorgement was based on some or all of the following: subjective complaint of pain in the breast and objective evidence of breast swelling, induration and impaired lactation.</p>
Interventions	<p>Intervention group (n = 35): oral serrapeptase (Danzen), an anti-inflammatory proteolytic enzyme drug derived from serratia E15 (isolated from the silk worm intestine) was administered in a dose of 2 tablets (5 mg per tablet) 3 times a day for 3 days.</p> <p>Control group (n = 35): specially made tablets that were identical in appearance to the Danzen tablets were given according to the same regimen.</p> <p>During the study breastfeeding was encouraged and concomitant breast massage and milk expression was allowed.</p> <p>Duration of treatment: 3 days</p> <p>Duration of follow-up: 3 days</p> <p>Adverse events: "There were no adverse reactions to the drug reported by any of the patients given either Danzen or placebo."</p>
Outcomes	<p>Total improvement of breast engorgement</p> <p>Improvement of individual symptoms:</p> <ul style="list-style-type: none"> ◦ improvement of breast induration; ◦ improvement of breast swelling; and ◦ improvement of breast pain.
Notes	<p>The authors gave cumulative percentages in the results section, which the review authors corrected. The study authors reported that breastfeeding was encouraged during the study but they reported that only 4 patients in the treatment group and 8 in the placebo breastfed their babies during the study period.</p> <p>No adverse reactions were reported by any of the patients given Danzen.</p> <p>Dates of study: not reported</p> <p>Funding sources: Takeda Chemical Industries, Ltd. acknowledged for supplying the Danzen (serrapeptase) tablets</p> <p>Declarations of interest: not reported</p> <p>No correspondence email. Journal in which study published contacted but author details no longer stored.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised controlled trial but random sequence generation not adequately described

Treatments for breast engorgement during lactation (Review)

Kee 1989 (Continued)

Allocation concealment (selection bias)	Unclear risk	Allocation concealment not defined
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"The placebo tablets were specially manufactured for the study and were identical in appearance to Danzen tablets." "None of the research team was aware of the respective identification during the duration of the study."
Blinding of outcome assessment (detection bias)	Low risk	"An independent observer, unaware of the groups the patients were in, assessed each symptom and sign daily."
Incomplete outcome data (attrition bias) All outcomes	Low risk	The authors reported on all outcomes.
Selective reporting (reporting bias)	Low risk	The authors reported on all outcomes and all participants.
Other bias	Unclear risk	Role of sponsor unclear. Presumably provided tested drugs. Possible vested interest may have lead to a risk of bias in favour of tested drug.

Ketsuwan 2018
Study characteristics

Methods	Randomised controlled trial. Single-centre study
Participants	<p>No. of participants: 500 women</p> <p>Setting: postpartum ward of Baby Friendly Hospital in rural Thailand</p> <p>Inclusion criteria: uncomplicated delivery of newborn weighing more than 2500 g; grade 3 breast engorgement (breast very painful, has large distension, and moderate oedema) or grade 4 (breast extremely painful, has marked distention, and severe oedema); no use of analgesics or NSAIDs at least 6 h prior to treatment</p> <p>Exclusion criteria: mothers whose infants were diagnosed with galactosaemia</p>
Interventions	<p>Intervention group (n = 250): a hot herbal ball, wrapped in a towel, was gently rolled by the nurse against the participant's breast, avoiding the nipple areolar complex. When the ball cooled down it was replaced with a second steaming hot ball. The 2 herbal balls were alternately compressed and steamed for a total treatment duration of 20 min. The contact time for each compression was approx. 10s. The main ingredients of the herbal balls were Cassumunar ginger, turmeric and camphor. Treatment was started within 30 min of diagnosis of breast engorgement.</p> <p>Control group (n = 250) same procedure but with hot ball-like towels instead of herbal balls</p> <p>Duration of treatment: 20 mins</p> <p>Duration of follow-up: same as treatment duration</p> <p>Adverse events: "There were two cases (0.8%) with skin irritation in the herbal compress group and no cases...in the hot compress group. The skin irritation resolved without any additional treatment at the 24-h follow-up".</p>

Ketsuwan 2018 (Continued)

Outcomes	Breast pain measured using a visual analogue scale, ranging from 1 (no breast pain) to 10 (severe breast pain). Pain scores were assessed immediately before and after breast engorgement treatment. Adverse events recorded 24 h after treatment
Notes	<p>Dates of study: July, 2016 to October, 2017</p> <p>Funding sources: Srinakharinwirot University</p> <p>Declarations of interest: "No competing financial interests exist."</p> <p>Corresponding author contacted 20.11.2019 and 16.12.2019. to clarify funding sources and RoB. Reply received 17.12.2019</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation was done using a computer-generated list".
Allocation concealment (selection bias)	Low risk	"Sequentially numbered sealed envelopes"; author contacted and envelopes confirmed to be opaque
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Small towels were prepared and packed as herbal balls", but given the volatile oils in the herbal balls it was unlikely that participants were blinded to group allocation. According to the study author, nurses prepared the herbal balls and hot packs, therefore, personnel were not blinded either.
Blinding of outcome assessment (detection bias)	High risk	"Mothers were asked by nurses to place a line perpendicular to the VAS line..." and since mothers were most likely aware of group allocation, detection bias is high.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Authors reported on all outcomes.
Other bias	Low risk	Unlikely

Khosravan 2017

Study characteristics

Methods	Randomised, controlled, clinical trial. Multicentre study
Participants	<p>No. of participants: 47 postpartum women with breast engorgement</p> <p>Setting: women were recruited from hospitals and health centres in Iran</p> <p>Inclusion criteria. Mother: 1st 15 days post-delivery, minimum breast engorgement intensity score of 2, temperature < 38°C, no use of medications for stopping breastfeeding, no use of topical herbal therapies, no abscess or mastitis, no contraindications to breastfeeding, no allergies to hollyhock or other plants, breastfeeding every 2-3 hours. Infant: full-term, singleton pregnancy, normal birthweight, able to suck, no contraindications to breastfeeding, responsively fed</p>

Khosravan 2017 (Continued)

Exclusion criteria: allergy to hollyhock, high grade fever, use of analgesics or NSAIDs, any event interfering with ability to breastfeed. **Infant:** fever during course of intervention

Interventions	<p>Intervention group (n = 20): routine care, then 10 to 15 min later, 40-50 mL of hollyhock leaf herbal compress rubbed on the breast and removed within 10 min. Procedure repeated 3 x day for 2 days</p> <p>Control group (n = 20): routine care - warm compress (T43-6°C) applied to engorged breast for 2 min; baby breastfed half an hour later, with simultaneous massage ("from top to nipple"); after breastfeed, cold compress (10-8°C) applied for 15-20 min., with compress soaked in cold water every 2 min and then reapplied</p> <p>Hollyhock solution: 10 g of powder mixed with cooled boiled water. Ready for use within 30 min. Powder consists of hollyhock leaves and stems, dried at 60°C for 24 h, milled to a powder and irradiated with ultraviolet light for 30 min.</p> <p>Mothers in both groups advised to nurse their infants from both breasts every 2-3 hours for 10-15 min</p> <p>Intervention performed by participants</p> <p>Duration of treatment: 1-1.5 h, 3 times a day for 2 days</p> <p>Duration of follow-up: 2 days</p> <p>Adverse events: not reported</p>
Outcomes	<p>Severity of breast engorgement: a total score ranging between 0 and 19 for breast erythema, tension and pain. Erythema: 0 for "no redness", 1 for "redness in patches", 2 for "full redness in a limited area", 3 for "shiny redness in a limited area", 4 for "shiny redness over most of the breast" Tension: 0 for "no changes", 1 for "firm and no tenderness", 2 for "tense but not uncomfortable", 3 for "tense and uncomfortable", 4 for "tense and painful", 5 for "very tense and very painful". Pain: "score between 0 and 10". Outcome assessed by participants (self-assessment)</p>
Notes	<p>Dates of study: not reported</p> <p>Funding sources: Research Administration of Gonabad University of Medical Sciences, Gonabad, Iran</p> <p>Declarations of interest:</p> <p>"The authors declare to have no conflicts of interest with respect to the research, authorship, and/or publication of the article."</p> <p>Corresponding author contacted 21.11.2019 and 16.12.2019 to provide dates of study and clarify RoB - no reply</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Study subjects were randomly divided into an intervention group and a control group using blocks of 4".
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Participants received instructions on performing the interventions at home..."
Blinding of outcome assessment (detection bias)	High risk	"Participants received instructions on evaluating their breast engorgment..."

Treatments for breast engorgement during lactation (Review)

Khosravan 2017 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	All but 1 missing participant accounted for; attrition almost identical in both groups; reasons for attrition stated and unlikely to influence outcome
Selective reporting (reporting bias)	Low risk	Expected outcomes reported
Other bias	Unclear risk	Some women were excluded for not having performed the intervention properly.

Kumari 2019

Study characteristics

Methods	Quasi-experimental study. Single-centre study
Participants	<p>No. of participants: 63 women with breast engorgement</p> <p>Setting: women were recruited from a postnatal ward in New Delhi, India</p> <p>Inclusion criteria: women with breast engorgement as assessed by 6-point breast engorgement scale and numeric pain scale</p> <p>Exclusion criteria: not reported</p>
Interventions	<p>Intervention group (n = 32): room temperature green cabbage leaves applied for 15 min., 6 times over 2 days, with 6-hour gaps</p> <p>Control group (n = 31): hot water bag applied for 15 min., 6 times over 2 days, with 6-hour gaps</p> <p>Duration of treatment: 36 hours</p> <p>Duration of follow-up: same as duration of treatment</p> <p>Adverse events: not reported</p>
Outcomes	Breast engorgement and breast pain
Notes	<p>Dates of study: January to March, 2012</p> <p>Funding sources: self-funded</p> <p>Declarations of interest: "Conflict of Interest – Nil"</p> <p>Corresponding author contacted 21.11.2019 and 16.12.2019 for clarification of RoB - no reply</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information: "...subjects who fulfilled inclusion criteria were selected consecutively and randomly assigned to either Experimental or Control group".
Allocation concealment (selection bias)	Unclear risk	Insufficient information

Kumari 2019 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Mothers applied either room temperature GCL or HWB, therefore, aware of allocation
Blinding of outcome assessment (detection bias)	High risk	Unclear who conducted assessment but presumably mothers, therefore, not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Low risk	All expected outcomes reported
Other bias	Low risk	No other bias identified

Kvist 2004
Study characteristics

Methods	Randomised controlled trial. Multicentre study
Participants	<p>No. of participants: 88 women</p> <p>Setting: breastfeeding clinics in the south of Sweden</p> <p>Inclusion criteria: at least 2 of the following symptoms of breast inflammation: erythema, tension, resistance, pain or pyrexia</p> <p>Exclusion criteria (contraindications for acupuncture treatment): psychiatric illness, haemorrhagic disease, prosthetic heart valves, infections of the skin, hepatitis B or HIV</p>
Interventions	<p>Group 1 (n = 28): usual care, including oxytocin nasal spray at the discretion of attending midwives</p> <p>Group 2 (n = 35): acupuncture to points HT 3 (heart) and GB 21 (gall bladder)</p> <p>Group 3 (n = 25): acupuncture to points HT 3, GB 21 and SP 6 (spleen).</p> <p>Acupuncture was carried out by midwives with acupuncture experience.</p> <p>All 3 groups received advice on interval and duration of breastfeeds, breast emptying and application of unrefined cotton wool.</p> <p>Duration of treatment: up to 30 min</p> <p>Duration of follow-up: until symptoms had subsided</p> <p>Adverse events: not reported</p>
Outcomes	Severity of engorgement symptoms on day 3 expressed as severity index (sum of scores for breast tension, erythema and pain); maternal satisfaction with breastfeeding; breast tissue resistance
Notes	<p>Published results were not reported in a way that we were able to use in data tables. Results stated that there were no differences between groups at day 3, but no original data were presented. We contacted the author for further information; data from the study were no longer available.</p> <p>Dates of study: January 2001 - January 2002</p>

Kvist 2004 (Continued)

Funding sources: the study was supported by 'The milk drop' in Helsingborg, Sweden, and NIDAB Baby Bag.

Declarations of interest: "No conflicts of interest"

Corresponding author contacted 21.11.2019 re DoI statement - invalid email. Contacted 23.5.2020. Response received

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A total of 150 opaque envelopes, 50 for each group, were prepared with a paper denoting the intervention group and sealed. These were then randomly mixed and the envelopes numbered. The envelopes were identical in weight. For those wishing to take part, the midwife opened an envelope in correct numerical order, in the mothers' presence."
Allocation concealment (selection bias)	Low risk	Described as sealed opaque envelopes opened by midwives in order
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible. "Blinding of participants was not attempted in this study because the practice of sham acupuncture has been questioned for its reliability."
Blinding of outcome assessment (detection bias)	High risk	"The treating midwife completed protocols for the mothers' initial visit to the clinic and for every follow-up contact until the mother reported that symptoms had subsided."
Incomplete outcome data (attrition bias) All outcomes	High risk	Could not be measured. 88 women randomised. Denominators for results not clear. No post-intervention tables provided. Study was ended prematurely partly due to "the realization that the number of patients referred to the doctor for prescription of antibiotics was small".
Selective reporting (reporting bias)	High risk	Breast tissue resistance was not reported in the results even though a scale was devised to measure it. Non-significant results were mentioned but not reported adequately.
Other bias	Unclear risk	Study report not very clear to allow identification of other potential sources of bias

Kvist 2007
Study characteristics

Methods	Randomised, non-blinded 3-arm controlled trial. Single-centre study
Participants	<p>No. of participants: 210</p> <p>Setting: hospital breastfeeding clinic in the south of Sweden</p> <p>Inclusion criteria: at least 2 of the following symptoms: breast erythema, tension, resistance, pain or pyrexia</p> <p>Exclusion criteria (contraindications for acupuncture treatment): psychiatric illness, haemorrhagic disease, prosthetic heart valves, infections of the skin, hepatitis B or HIV</p>

Kvist 2007 (Continued)

Interventions	<p>Essential care to everyone: advice on duration and frequency of breastfeeds, advice on breast emptying (manual expression, pumping or warm shower) and application of unrefined cotton wool</p> <p>Group 1 (n = 70): essential care and oxytocin nasal spray, at the discretion of the clinical staff</p> <p>Group 2 (n = 70): essential care and acupuncture, avoiding the SP6 site which stimulates oxytocin</p> <p>Group 3 (n = 70): essential care and acupuncture, including the SP6 site.</p> <p>The acupuncture was performed by midwives who had completed a course in obstetrical acupuncture and had at least 5 years experience in its use.</p> <p>Duration of treatment: up to 30 min</p> <p>Duration of follow-up: 6 weeks</p> <p>Adverse events: not reported</p>
Outcomes	Severity index (sum of scores for breast tension, erythema and pain) on days 3, 4 and 5; number of contact days till recovery; maternal satisfaction with breastfeeding on days 3, 4 and 5; need for antipyretics; number of contact days till recovery; residual symptoms after 6 weeks; occurrence of breast abscess; need for antibiotics
Notes	<p>The authors included 5 women, who were randomised twice because they developed residual symptoms after 6 weeks, to the original 205 participants to give 210 episodes of inflammatory symptoms.</p> <p>Dates of study: 2002 - 2004</p> <p>Funding sources: Stig and Ragna Gorthon Foundation, Helsingborg, Sweden, provided research grants.</p> <p>Declarations of interest: "No conflicts of interest"</p> <p>Corresponding author contacted 21.11.2019 for DoI statement and clarification of blinding - invalid email. New email obtained and author contacted 23.5.2020</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Envelopes prepared in advance. These were then randomly mixed and the envelopes numbered.
Allocation concealment (selection bias)	Low risk	Opaque envelopes were used to allocate women into the 3 groups. "The sequence of group allocation was not known to anyone."
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>The nature of the trial did not allow blinding. Women who were getting acupuncture would know their intervention.</p> <p>The authors did not mention blinding of clinical staff but the nature of the study would not allow blinding of clinical staff.</p>
Blinding of outcome assessment (detection bias)	High risk	The authors did not mention blinding of outcome assessors. Author contacted: "The outcome assessors for the 2007 paper were not blinded".
Incomplete outcome data (attrition bias) All outcomes	Low risk	The authors reported about dropouts and they reported that they did ITT analysis.
Selective reporting (reporting bias)	Low risk	The authors reported on all prespecified outcomes.

Treatments for breast engorgement during lactation (Review)

Kvist 2007 (Continued)

Other bias	Low risk	No other bias identified
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McLachlan 1991
Study characteristics

Methods	Randomised double-blind, placebo-controlled trial. Analysis per breast rather than women. Single-centre study
Participants	<p>No. of participants: 109 women who were referred to the physiotherapist for treatment of breast engorgement</p> <p>Setting: Monash Medical Centre, Melbourne, Australia</p> <p>Exclusion criteria: spoken or written English insufficient for informed consent; breast implants</p>
Interventions	<p>Group 1 (n = 22): both breasts received ultrasound treatment. Medtron model P300 ultrasound machine used with aquasonic ultrasound transmission gel as coupling agent. Intensity was adjusted to give a comfortable warmth; application head massaged over breast towards areola; firmer pressure used on inwards stroke; duration of treatment ranged from 8 min for A cup to 15 min for breast of DD or greater cup size.</p> <p>Group 2 (n = 23): both breasts received sham treatment. Ultrasound machine of identical appearance used in the same way as described above; the control machine had the crystal removed and replaced with a resistor to produce surface heat only.</p> <p>Group 3 (n = 64): 1 breast received ultrasound and 1 breast received sham treatment.</p> <p>Duration of treatment: 8-15 min, daily, up to 6 times</p> <p>Duration of follow-up: 24 h after final treatment</p> <p>Adverse events: not reported</p>
Outcomes	Breast pain measured using a VAS; breast hardness measured using a digital tonometer. Outcomes measured before and after treatment, prior to breastfeeding
Notes	<p>Each breast, instead of an individual woman, was the unit of analysis. The machines were labelled as A and B and were changed weekly by someone blind to allocation of women.</p> <p>Dates of study: not reported</p> <p>Funding sources: ultrasound machines used in the study were donated by Metronex Engineering Pty Ltd. Financial support was acknowledged from the Queen Victoria Medical Centre's Research Committee and the Obstetrics and Gynaecology Special Interest Group of the Australian Physiotherapy Association.</p> <p>Declarations of interest: not reported</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Balanced block randomisation sequence."
Allocation concealment (selection bias)	Unclear risk	The authors did not mention allocation concealment.

Treatments for breast engorgement during lactation (Review)

McLachlan 1991 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	"The serial numbers of the machines were covered and the machines were labelled A and B. Labels were changed weekly by the Head of Department who had no role in the ultrasound treatment and did not hold the trial log book. The woman's name was given to the clerical officer who held the trial log book. She informed the treating physiotherapist which machine to use. (A or B)."
Blinding of outcome assessment (detection bias)	Low risk	The outcome assessor was blinded to the groups the women were in.
Incomplete outcome data (attrition bias) All outcomes	High risk	The authors mentioned that 3 women were lost to follow-up but they did not say how that was handled.
Selective reporting (reporting bias)	Low risk	The authors reported all the prespecified outcomes.
Other bias	High risk	Results were very difficult to interpret as analysis was by breast. The authors also stated that when the VAS was used, it was not always easy for women to make a clear distinction between the left and the right breast.

Meng 2015

Study characteristics

Methods	Randomised, controlled trial. Single-centre study
Participants	<p>No. of participants: 200 women with puerperal milk stasis</p> <p>Setting: women were recruited from the obstetric outpatient clinic of the Southwest Hospital in China</p> <p>Inclusion criteria: singleton pregnancy, no pregnancy complications, no taboos about breastfeeding, normally suckling infant, localised milk stasis characterised by red and painful breast lumps</p> <p>Exclusion criteria: mothers with allergy to aloe and cactus, breast abscess, breast tumour, haematoma, skin burn</p>
Interventions	<p>Group 1 (n = 62): breast massage, alternating with cactus and aloe cold compress. Thin slices of fresh aloe and peeled cactus were applied to the breast for 15 min before and after massage.</p> <p>Group 2 (n = 78): cactus and aloe cold compress only</p> <p>Group 3 (n = 60): breast massage only</p> <p>All treatments conducted by physician</p> <p>Duration of treatment: Approx. 1 h/d for 7 days</p> <p>Duration of follow-up: 7 days</p> <p>Adverse events: not reported</p>
Outcomes	<p>1. Breastfeeding status: complete breastfeeding, mixed feeding, complete formula feeding</p> <p>2. Breast hardness: level 1 - similar to touching the lips with little or no pain; level 2 - similar to touching the nose with a moderate degree of pain; level 3 - similar to touching the forehead with severe pain</p> <p>3. Breast tenderness: VAS - mild pain < 4, moderate pain 4-7, severe pain 7-10</p>

Meng 2015 (Continued)

Notes

Dates of study: January 2013 to July 2014

Funding sources: not reported

Declarations of interest: "The authors declare no conflict of interest".

Corresponding author contacted 21.11.2019 and 19.12.2019 - no response

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information; "patients were randomly divided"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel aware of allocation
Blinding of outcome assessment (detection bias)	High risk	Assessor aware of allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	48 participants lost to follow-up and not accounted for
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported
Other bias	Low risk	No other bias identified

Monazzami 2019

Study characteristics

Methods	Randomised controlled trial. Single-centre study
Participants	<p>No. of participants: 76 women</p> <p>Setting: women were recruited from the obstetrics and gynaecology department of a university hospital in Iran</p> <p>Inclusion criteria: Iranian nationality and resident in Mashhad (Iran); consent to participate in the study; able to read and write; having a 2-5 day old infant; gestational age 37-42 weeks; normal weight (2500-4000 g), no contraindications to breastfeeding; mother is breastfeeding and intends to continue breastfeeding; no specific diseases that could interfere with breastfeeding; no delivery complications; no history of breast surgery; no breast abscess or mastitis, min. score of '2' for breast engorgement, not taking medications which inhibit lactation, not applying any creams to breasts</p> <p>Exclusion criteria: maternal body temperature > 38°C during the intervention, breastfeeding intervals > 3 h, unwilling to cooperate, intervention conducted less than 5 times, less than 6 or more than 8 h elapsed between interventions, lack of access to research unit 12-24 h after intervention, allergy to ginger, mastitis, stressful event during study, neonatal complications that interfere with breastfeeding</p>

Monazzami 2019 (Continued)

Interventions	<p>Intervention group (n = 38): warm ginger compress (10 g ginger powder added to 100 mL boiled water) placed on engorged breast for 30 min</p> <p>Control group (n = 38): usual care (education on proper breastfeeding technique, application of hot compress)</p> <p>Duration of treatment: 30 min, 3 X day for 2 consecutive days</p> <p>Duration of follow-up: 2 days</p> <p>Adverse events: not reported</p>
Outcomes	Severity of breast engorgement measured using Engorgement Severity Standard Index. Results reported per individual breast
Notes	<p>Dates of study: 2018</p> <p>Funding sources: Mashahd University of Medical Sciences</p> <p>Declarations of interest: not reported</p> <p>Report kindly translated by members of Cochrane Iran</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Participants have been assigned randomly to the case and control group".
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not addressed in the text.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Blinding is not performed because of type of intervention (smell and color of ginger) and number using the intervention, ..."
Blinding of outcome assessment (detection bias)	High risk	Blinding not performed
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition
Selective reporting (reporting bias)	Low risk	There was consistency between protocol (IRCT20180508039585N1) and the report.
Other bias	High risk	The data were analysed at the breast level with no adjustment for the non-independence of breasts. As mentioned in McLachlan 1991 , when the VAS was used, it was not always easy for women to make a clear distinction between the left and right breast.

Murata 1965

Study characteristics

Treatments for breast engorgement during lactation (Review)

Murata 1965 (Continued)

Methods	Quasi-randomised trial. Women allocated to different groups on alternate days. Experimental group on even number days and placebo on odd number days. Single-centre study
Participants	<p>No. of participants: 59 women</p> <p>Setting: Ota General Hospital, Japan</p> <p>Inclusion criteria: breast engorgement defined as "mammary swelling or induration" ... "complaining of pain or tenderness"), 3rd to 5th day post-delivery</p>
Interventions	<p>Intervention group (n = 35): day 1: 2 tablets of protease complex, an enteric-coated tablet consisting of bromelain and trypsin, taken 4 times a day (after each meal and before bed time); day 2 and 3: 1 tablet 4 times a day; total of 16 tablets</p> <p>Control group (n = 24): lactose-containing placebo tablets given according to above regimen</p> <p>Duration of treatment: 3 days</p> <p>Duration of follow-up: 4 days</p> <p>Adverse events: none were observed with regard to gastrointestinal troubles or poor uterine involution.</p>
Outcomes	Breast swelling and pain measured on the afternoon of the 4th day; maternal opinion of treatment; size of breast; shape of nipple; coagulation, prothrombin and bleeding time
Notes	<p>It was not clear whether all women were breastfeeding. The outcomes were measured using grades according to the degree of improvement of symptoms. In situations where there was no change, the grade allocated was 0, where the symptoms became worse, the grade was - 1, in cases where there was a 1 stage improvement, the grade given was 1 and where there was a 2 stage improvement, the grade was 2.</p> <p>No change was detected before and after treatment in regard to coagulation, prothrombin and bleeding time.</p> <p>Dates of study: not reported</p> <p>Funding sources: Protease complex tablet was supplied by Mochida Pharmaceutical Company.</p> <p>Declarations of interest: not reported</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-randomisation, allocation by day of the week. This method introduced bias in the way the participants were allocated to different groups.
Allocation concealment (selection bias)	High risk	Group allocation could be anticipated in advance as it was known which arm of the study was allocated to which day of the week.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study was placebo-controlled but the authors did not mention whether the placebo was identical to the treatment or if it was easy for women to see what they were getting. There was no mention of blinding of the clinician who administered the treatment.
Blinding of outcome assessment (detection bias)	Low risk	2 outcome assessors recorded the change in swelling and pain on the 4th day and were not informed as to which participant belonged to which group.
Incomplete outcome data (attrition bias)	Low risk	There were no exclusions and no losses to follow-up.

Treatments for breast engorgement during lactation (Review)

Murata 1965 (Continued)

All outcomes

Selective reporting (reporting bias)	Low risk	The authors reported on all prespecified outcomes.
Other bias	Unclear risk	Protease complex tablet was supplied by Mochida Pharmaceutical Company under the trademark 'Kimotab'. Possible vested interest may have lead to a risk of bias in favour of tested drug.

Roberts 1995a
Study characteristics

Methods	Quasi-randomised trial (breasts rather than women were the unit of analysis). Multicentre study
Participants	<p>No. of participants: 28 lactating women with breast engorgement</p> <p>Setting: inpatients recruited from 2 hospitals in Darwin, Australia, usually on the 3rd day postpartum</p> <p>Inclusion criteria: breastfeeding, and engorged breasts, defined as "hard, very warm, painful breasts, with difficulty feeding", according to the professional judgment of the midwives caring for them.</p> <p>Exclusion criteria: Aboriginal women</p>
Interventions	<p>Group 1: chilled cabbage leaves were placed on the right breast and room temperature cabbage leaves were placed on the left breast for 2 hours.</p> <p>Group 2: cabbage leaves placed on breasts in reverse order for 2 hours.</p> <p>Cabbage leaves applied between feedings. Cabbage leaves, from common green cabbages (<i>Brassica oleracea</i>), were prepared by stripping out the large vein, cutting a hole for the nipple, rinsing, and chilling or leaving at room temperature.</p> <p>Duration of treatment: 2 h</p> <p>Duration of follow-up: same as duration of treatment</p> <p>Adverse events: not reported</p>
Outcomes	Pain: pre-treatment measurement; post-treatment measurement 2 hours later
Notes	<p>This was a convenience sample of lactating women with breast engorgement. All women had both treatments and analyses were for individual breasts rather than for women. As breasts are not independent, results were very difficult to interpret. Pre-test assessments were for 28 women whereas post-test assessments were for 56 breasts. Data were not in a form in which we were able to enter them into data tables.</p> <p>Dates of study: not reported</p> <p>Funding sources: not reported</p> <p>Declarations of interest: not reported</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described

Treatments for breast engorgement during lactation (Review)

Roberts 1995a (Continued)

Allocation concealment (selection bias)	Unclear risk	The authors did not state how allocation concealment was done.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants was not feasible. All women had both treatments - 1 on each breast and the treatments were not identical as 1 was cold and 1 was room temperature cabbage leaves. Blinding was not feasible as women either received cold or room temperature cabbage leaves.
Blinding of outcome assessment (detection bias)	High risk	Women were assessing their breast on a VAS and midwives were supervising.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The authors reported on all participants included in the study.
Selective reporting (reporting bias)	Low risk	The authors reported on all outcomes.
Other bias	High risk	Analysis was by breast rather than by women. Breasts are unlikely to be independent, especially in terms of outcomes reported in this study. As mentioned in McLachlan 1991 , when a VAS was used, it was not always easy for women to make a clear distinction between the left and the right breast.

Roberts 1995b
Study characteristics

Methods	Quasi-randomised trial (breasts rather than women were the unit of analysis). Multicentre study
Participants	No. of participants: 34 lactating women Setting: postnatal wards in 2 hospitals in Darwin, Australia Inclusion criteria: non-Aboriginal, lactating, suffering from breast engorgement (hard, warm, painful breasts, with difficulty feeding), according to the professional judgement of the midwives caring for them
Interventions	Group 1 (even hospital registration numbers): chilled gel pack on the right breast and chilled cabbage leaves on the left breast Group 2 (odd hospital registration numbers): opposite to above. Leaves from common green cabbages were prepared by stripping out the large vein, cutting a hole for the nipple, rinsing and chilling. Breast-shaped gel pack in small, medium, and large sizes were designed by the researcher to fit under the brassiere, covering the breast except for the nipple area. Treatment left on breasts for up to 8 hours, with mothers renewing the cabbage leaves and gel packs ad lib, usually every 2 to 4 hours Duration of treatment: 8 h Duration of follow-up: same as duration of treatment Adverse events: not reported

Treatments for breast engorgement during lactation (Review)

Roberts 1995b (Continued)

Outcomes	Pre and post-test breast pain rating for each breast rated on a "pain ruler" (a VAS with numbers from 0-10, labelled with descriptions: 0 = no pain, 5 = moderate pain, and 10 = excruciating pain). Descriptive data about mothers' symptoms of engorgement and opinion of treatment were also collected.
Notes	<p>Analysis was at the breast level and results were at high risk of bias and difficult to interpret. We have not been able to include data in the data tables.</p> <p>Dates of study: not reported</p> <p>Funding sources: not reported</p> <p>Declarations of interest: not reported</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-randomisation (by hospital number)
Allocation concealment (selection bias)	High risk	"Random allocation to groups was not considered necessary".
Blinding of participants and personnel (performance bias) All outcomes	High risk	The nature of the study did not allow blinding of women or clinicians.
Blinding of outcome assessment (detection bias)	High risk	Participants rated outcomes in a self-administered questionnaire. Given that visibly different interventions were placed on each breast, blinding of participants/outcome assessors was not possible.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The authors reported on all outcomes.
Selective reporting (reporting bias)	Low risk	No other identified bias
Other bias	High risk	The data were analysed at the breast level with no adjustment for the non-independence of breasts. As mentioned in McLachlan 1991 , when the VAS was used, it was not always easy for women to make a clear distinction between the left and right breast.

Roberts 1998
Study characteristics

Methods	Double-blind randomised controlled trial. Multicentre study
Participants	<p>No. of participants: 39 lactating, postpartum women with breast engorgement. Breast engorgement defined as hard, warm, painful breasts with difficulty feeding</p> <p>Setting: postnatal wards at Royal Darwin Hospital and Darwin Private Hospital, Australia</p> <p>Exclusion criteria: Aboriginal women (tend to have less breast engorgement), women allergic to roses or the cabbage family of plants.</p>

Treatments for breast engorgement during lactation (Review)

Roberts 1998 (Continued)

Majority were multiparas with prior breastfeeding experience, who reported the appearance of engorgement symptoms on day 3 postpartum. Significantly more primiparas were in the intervention group.

Interventions	<p>Intervention group (n = 21): base cream with 1% cabbage leaf extract (according to British Pharmacopoeia formulation)</p> <p>Control group (n = 18): base/placebo cream only</p> <p>Rosewater added to both creams to camouflage residual odour of cabbage.</p> <p>1 tube of cream was applied liberally to both breasts and left on for 2 hours. The 2-hour period was chosen since cabbage leaves had been shown to act within this period of time, and it could be done within the inter-feeding period.</p> <p>Mothers were asked to refrain from showers, analgesia and feeding the baby during this period.</p> <p>Duration of treatment: 2 h</p> <p>Duration of follow-up: same as duration of treatment</p> <p>Adverse events: not reported</p>
Outcomes	<p>Breast pain, using Bourbonnais pain scale (a VAS)</p> <p>Chest circumference, using plastic tape measure</p> <p>Degree of hardness, using Roberts durometer</p> <p>Degree of engorgement, using Hill and Humenick Breast Engorgement Scale</p> <p>Outcomes measured at baseline, 2 hours after application of cream and following subsequent breast-feed</p>
Notes	<p>Authors were contacted to clarify method of cream application, i.e. to elucidate whether application method (e.g. massage) contributed to treatment effect. According to authors "the cream was lightly rubbed in, not massaged, just enough pressure to have the cream absorbed".</p> <p>Authors were also contacted to confirm that results shown in Table 3 refer to post-test measurements (not stated in manuscript), and to check whether there were any significant differences between experimental and control groups for pre-test values (given as a combined measure, in Table 4). Precise data on the latter could not be provided, since Australian regulations require data be kept for 5 years only post-publication, but according to trial authors no differences were detected.</p> <p>The authors reported that breastfeeding had a better effect than application of cream in relieving discomfort and decreasing tissue hardness.</p> <p>Dates of study: not reported</p> <p>Funding sources: Blackmores Natural Products provided a research grant and prepared the creams.</p> <p>Declarations of interest: not reported</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomised assignment list generated using coin toss."
Allocation concealment (selection bias)	Unclear risk	"Group assignments were placed in sealed envelopes" but type of envelope not stated (transparent or opaque)

Roberts 1998 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Women did not know which cream they were using as the creams were identical in colour and odour. The same midwife applied the cream and performed the measurements. The midwife was however blinded to the groups the women were in.
Blinding of outcome assessment (detection bias)	Low risk	The midwife who assessed the outcomes was blinded to the allocations.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss of data
Selective reporting (reporting bias)	Unclear risk	All outcomes were reported but in a form that could not be easily interpreted. Pre-test measurements for each outcome were given as a single value, i.e. for both groups combined, so change in outcome measures could not be accurately calculated.
Other bias	High risk	A significant imbalance in primiparas at baseline ($P = 0.047$) may have been due to chance but may also have been due to possible allocation concealment bias or compromised blinding.

Robson 1990
Study characteristics

Methods	Randomised controlled trial. Single-centre study
Participants	<p>No. of participants: 88 breastfeeding mothers with "varying degrees" of breast engorgement</p> <p>Setting: hospital, USA</p> <p>Exclusion criteria: oriental ethnic background (it was not clear how many women were excluded for this reason)</p>
Interventions	<p>Intervention group (n = 45): breast-shaped cold packs worn 15-20 min after 2 consecutive feeds</p> <p>Control group (n = 43): routine care which encouraged the use of supportive bras, warm compresses, manual expression/pumping of breasts, demand feeding and night time feeding, with intervals between feeds not being longer than 5 hours and each feed taking 30 min to 1 hour</p> <p>Duration of treatment: 15-20 min. after 2 consecutive feeds</p> <p>Duration of follow-up: unclear</p> <p>Adverse events: not reported</p>
Outcomes	<p>Pre- versus post-test breast pain scores. Scores were not reported in a way in which we were able to include them in data tables. We have briefly summarised the results in the text of the review.</p> <p>Transfer of milk</p> <p>Degree of engorgement</p>
Notes	<p>This study was at high risk of bias. Women in the intervention group who were most distressed were moved into the control group, and those in the control group who wanted packs were moved to the intervention group.</p> <p>Dates of study: not reported</p>

Robson 1990 (Continued)

Funding sources: not reported

Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Table of random numbers generated but randomisation sequence was not observed. 8/88 women were not allocated according to randomisation schedule but according to preferred treatment arm.
Allocation concealment (selection bias)	Unclear risk	The authors did not make mention of allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The nature of the study did not allow blinding of women or clinical staff.
Blinding of outcome assessment (detection bias)	High risk	A record of each participant was kept so that data could be analysed without their results.
Incomplete outcome data (attrition bias) All outcomes	High risk	There were serious protocol deviations and no ITT analysis.
Selective reporting (reporting bias)	Low risk	The authors reported on all prespecified outcomes.
Other bias	High risk	There was considerable baseline imbalance. Women in the control groups had much lower pre-test pain scores. This may be due to the fact that 3 women with the most severe symptoms were moved out of the control group and into the intervention group. There was no ITT analysis.

Sankanagoudar 2011
Study characteristics

Methods	Randomised, controlled study. Single-centre study
Participants	<p>No. of participants: 40 women with breast engorgement</p> <p>Setting: women were recruited from the obstetrics department of S.D.M. Hospital, India</p> <p>Inclusion criteria: symptomatic postpartum breast engorgement</p> <p>Exclusion criteria: malignant tumour of the breast, mastitis, breast abscess</p>
Interventions	<p>Intervention group (n = 20): non-thermal therapeutic ultrasound (2 consecutive days, between 10-15 min), in addition to breast massage (kneading of breast to elicit milk ejection reflex), manual expression (Marmet technique) and advice on appropriate feeding technique</p> <p>Control group (n = 20): breast massage (kneading of breast to elicit milk ejection reflex), manual expression (Marmet technique) and advice on appropriate technique</p> <p>Duration of treatment: 15 min/day for 2 days</p>

Sankanagoudar 2011 (Continued)

Duration of follow-up: 3 days

Adverse events: not reported

Outcomes	<p>1. Breast pain: measured with VAS</p> <p>2. Severity of engorgement: measured using 6-point engorgement scale (SPES)</p> <p>Measured each day pre and post-intervention for 2 consecutive days and on follow-up day 3 for both groups</p>
Notes	<p>Dates of study: not reported</p> <p>Funding sources: not reported</p> <p>Declarations of interest: not reported</p> <p>No corresponding email provided in article. Journal contacted (21.11.2019) and corresponding email requested. Journal editor replied and provided author email. Email sent 2.12.2019 and 28.12.2019 - no reply</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information: "They were randomly assigned to control and experimental group".
Allocation concealment (selection bias)	Unclear risk	As above
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel aware of allocation
Blinding of outcome assessment (detection bias)	Unclear risk	No mention of blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	The authors reported on all prespecified outcomes.
Other bias	Low risk	No other bias identified

Wong 2017
Study characteristics

Methods	Randomised, controlled 3-group pre-test and repeated post-test study design. Single-centre study
Participants	<p>No. of participants: 228 mothers</p> <p>Setting: private maternal hospital, Singapore</p>

Wong 2017 (Continued)

Inclusion criteria: mothers were 1) 21 y.o. or above; 2) breastfeeding; 3) developed breast engorgement within 14 days postpartum; 4) able to read, understand or speak English; 5) fulfilled 5 of 10 criteria using the Infant Breastfeeding Assessment Tool

Exclusion criteria: 1) mental disorder which may interfere with ability to participate in study; 2) taking lactation suppressants; 3) not breastfeeding; 4) medical condition causing pain or fever

Interventions	<p>Group 1 (n = 76): cold cabbage leaves (3 big, green, chilled cabbage leaves applied on top of each other to the whole of both breasts for 2 hours, followed by half hour break before repeat application) application plus routine care</p> <p>Group 2 (n = 76): cold gel packs (chilled gel pack applied to whole of each breast for 2 hours, followed by half hour break before repeat application) plus routine care</p> <p>Group 3 (n = 76): routine care only (antenatal classes, daily in-house postnatal classes during rounds conducted by lactation consultants, brochures in the hospital)</p> <p>Duration of treatment: 4 hours</p> <p>Duration of follow-up: 6 months</p> <p>Adverse events: not reported</p>
Outcomes	<ol style="list-style-type: none"> Breast pain (Numerical Rating Scale: 4-6 moderate pain, 7-10 severe pain) Breast hardness (Breast Engorgement Assessment Scale: 1 - breasts are soft and milk flows freely, 6 - breasts are very hard and painful and no milk flows. Score of 4 and above = breast engorgement) Body temperature (oral temperature; fever if > 38°C) Duration of breastfeeding (measured at 3 and 6 months postpartum) Satisfaction with care (6-point ordinal descriptive satisfaction scale)
Notes	<p>Dates of study: March 2013 to April 2014</p> <p>Funding sources: "This study received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors."</p> <p>Declarations of interest: "The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article."</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A block of randomisation of size 6 generated randomly by a biostatistician..."
Allocation concealment (selection bias)	Low risk	Assignment via "sequentially numbered, sealed, opaque envelopes"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not feasible due to nature of study
Blinding of outcome assessment (detection bias)	High risk	Nurses performing outcome assessment aware of allocation initially, but unaware at 3 and 6-month follow-up
Incomplete outcome data (attrition bias)	Low risk	All participants accounted for. Balanced attrition

Treatments for breast engorgement during lactation (Review)

Wong 2017 (Continued)

All outcomes

Selective reporting (reporting bias)	Low risk	All prespecified outcomes accounted for
Other bias	Low risk	Unlikely

BP: blood pressure

d: day

DoI: declaration of interest

GCL: green cabbage leaves

h: hour

HIV: human immunodeficiency virus

HWB: hot water bag

ITT: intention-to-treat

IU: international unit(s)

min: minutes

NSAID: nonsteroidal anti-inflammatory drug

ROB: risk of bias

SBES: severity of breast engorgement scale

T: temperature

VAS: visual analogue scale

y.o.: years old

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Booker 1970	This study focussed on the suppression of lactation in women who did not intend to breastfeed.
Filteau 1999	This study was examining interventions to prevent breast engorgement. Women in 3 villages were assigned 3 different treatments.
Gao 2018	This study focussed on localised milk stasis (blocked duct) only, i.e. on treating a breast "lump".
Garry 1956	This study focussed on an intervention for "drying up breasts" in women who did not intend to breastfeed.
KCT0002436	This study focussed on any postnatal women, not specifically those with breast engorgement.
King 1958	This study focussed on an intervention to suppress lactation in women who did not intend to breastfeed.
NCT032307602017	This study was not randomised.
Nikodem 1993	This study included 120 women on postnatal wards of a Johannesburg hospital, South Africa. Women were recruited 72 hrs after delivery. Women in the intervention group received cabbage leaves to their breasts versus routine care ("breast exercises") in the control group. The study was excluded as only approximately half of the sample perceived that they had symptoms of breast engorgement at baseline assessment. Cabbage leaves were therefore used as an intervention to prevent, as well as to treat, engorgement. Separate figures were not available for those women that had engorgement at the outset and were treated for symptoms. Results of this study suggested that women in the intervention group were more likely than those in the usual care group to be exclusively breastfeeding at 6 weeks (76% versus 58%).
Phillips 1975	This study only included women who had chosen not to breastfeed.

Study	Reason for exclusion
Roser 1966	It was not clear whether this study was an RCT. This study focused on an intervention to suppress lactation in women who did not intend to breastfeed; the treatment was commenced during labour, before the onset of any symptoms of breast engorgement.
Ryan 1962	In this study, women that were breastfeeding were excluded. The study focussed on an intervention to suppress lactation in women who did not intend to breastfeed.
Stenchever 1962	This study focussed on an intervention to suppress lactation in women who did not intend to breastfeed.

hrs: hours

RCT: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

[IRCT2017062633812N2](#)

Study name	Investigating the effect of Commiphora mukul cream on improvement of breast engorgement of women referred to the health center of Kerman University of Medical Science in 2015-2016
Methods	Randomised and triple-blinded
Participants	N = 100 Inclusion criteria: incidence of breast engorgement; term single birth pregnancies with normal weight; lack of abscess, fissure and mastitis; general temperature lower than 38°C and no allergy to Commiphora mukul Exclusion criteria: allergy to Commiphora mukul and Increased general temperatures more than 38°C
Interventions	A. Commiphora mukul: 0.5 mL Commiphora mukul cream will be rubbed to breast from the top to the nipple, 10 times a day for 2 days. B. Placebo cream: 0.5 mL placebo cream will be rubbed to breast from the top to the nipple 10 times a day for 2 days.
Outcomes	Breast engorgement score
Starting date	September 2016
Contact information	Shahrazad Zolala zolala@sbmu.ac.ir
Notes	Emailed trialist 18th November 2019

[IRCT20190608043838N1](#)

Study name	The effect of foot reflexology on the breast engorgement lactating mothers
Methods	A randomised clinical trial using 2-way blocking method with a control group, parallel groups and a sample size of 80 lactating mothers
Participants	N = 80

Treatments for breast engorgement during lactation (Review)

IRCT20190608043838N1 (Continued)

Inclusion criteria: lactating mothers in the first 3-5 days after delivery, healthy in terms of medical disease or obstetric issues, non-use of herbal topical drugs or chemicals, no mastitis, breast abscess and nipple scars, mothers with body temperature below 38°C, breast engorgement in the first 5 days after delivery, obtaining a minimum score of 2 out of 19 from the degree of engorgement checklist, non-use of antibiotics, breastfeeding, gestational age 37-42 weeks, age of a neonate 3-5 days, singleton birth

Exclusion criteria: the use or need of any anti-inflammatory drug, or the occurrence of mastitis or breast abscess during the study, non-lactation

Interventions	A. Foot reflexology B. Routine care
Outcomes	Breast engorgement severity
Starting date	September 2018
Contact information	Fatemeh Mousavi mousavif5@mums.ac.ir
Notes	Emailed trialist (mousavif5@mums.ac.ir) and sponsor (tafaghdim@mums.ac.ir) November 2019 but emails bounced back with error message that they were undeliverable.

NCT03985579

Study name	Influence of kinesiology taping application on severity of signs and symptoms in breast engorgement
Methods	Double-blind (masked roles: subject, outcomes assessor) Randomised
Participants	N = 60 Inclusion criteria: women 18 to 45 years of age, caesarean section or vaginal delivery, delivery between 37 and 41 gestational weeks, signs and symptoms of breast engorgement (significant increase of breast between 2nd and 10th day postpartum, pain, obstructed milk outflow), VAS 4 and more, volume of milk outflow less than 20 mL, 6-point self-rated engorgement scale between 3 and 6 Exclusion criteria: age less than 18 and more than 45, patients after extensive surgical breast intervention or having breast implants, allergy to kinesiology taping
Interventions	A. Standard care and kinesiology taping: application of elastic cotton strip with an acrylic adhesive that is used with the intent of treating pain and disability from athletic injuries and a variety of other physical disorders B. Standard care: assistance in baby feeding, manual of device-assisted (lactator) milk expression, cold compress, ibuprofen, gentle breast massage, breathing and shoulder girdle exercise
Outcomes	Change in pain (measured by VAS), human milk outflow change from baseline (based on infant body mass increase), 5-point perceived improvement scale
Starting date	July 1, 2019
Contact information	Anna Jakóbk

Treatments for breast engorgement during lactation (Review)

NCT03985579 (Continued)

a.jakobik@szpitalzelazna.pl

Notes	Emailed trialist 18th November 2019
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TCTR20181123001

Study name	Continuous ultrasound diathermy combined with conventional therapies versus conventional therapies alone for breast engorgement in postpartum lactating women: a randomised controlled study
Methods	Double-blind (masked roles: subject, outcomes assessor) Randomised
Participants	N = 72 Inclusion criteria: female, 18 to 50 years of age, breastfeeding, postpartum breast engorgement and blocked duct diagnosed by lactational specialist nurses Exclusion criteria: 1 Mastitis, breast abscess abnormal ultrasound findings suggest malignancy excluded by diagnostic breast ultrasound by radiologist 2 Family history of breast cancer first degree 3 Previous history of breast implant or augmentation 4 Accessory breast 5 History of previous ultrasound diathermy treatment 6 Impaired sensation in breast area 7 Impaired Thai language communication
Interventions	A. Continuous ultrasound diathermy, 1 mHz, Intensity (adjusted to proper warm sensation), duration 8-16 minutes combined with conventional therapies B. Sham ultrasound device combined with conventional therapies
Outcomes	Pain, hardness, level of difficulty of breastfeeding, breast engorgement severity, duration of breastfeeding, complications (mastitis, breast abscess)
Starting date	Registered November 2018. Actual start date unclear
Contact information	Dr Supattana Chatromyen dfondsupattana@gmail.com
Notes	Emailed trialist 18th November 2019

VAS: visual analogue scale

DATA AND ANALYSES

Comparison 1. Cabbage leaf treatments versus other treatments/placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Breast pain (0-10 VAS; higher score = more pain)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1.1 Room temperature cabbage leaves versus hot water bag	1	63	Mean Difference (IV, Fixed, 95% CI)	-0.16 [-0.39, 0.07]
1.1.2 Cold cabbage leaves versus routine care	1	152	Mean Difference (IV, Fixed, 95% CI)	-1.03 [-1.53, -0.53]
1.1.3 Cold cabbage leaves versus cold gel packs	1	151	Mean Difference (IV, Fixed, 95% CI)	-0.63 [-1.09, -0.17]
1.1.4 Cabbage leaf extract versus placebo cream	1	39	Mean Difference (IV, Fixed, 95% CI)	0.40 [-0.67, 1.47]
1.2 Breast hardness (higher score = more hardness)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.2.1 Cold cabbage leaves versus routine care	1	152	Mean Difference (IV, Fixed, 95% CI)	-0.58 [-0.82, -0.34]
1.2.2 Cold cabbage leaves versus cold gel packs	1	151	Mean Difference (IV, Fixed, 95% CI)	-0.24 [-0.48, -0.00]
1.3 Breast engorgement (measured with 6-point engorgement scale)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.3.1 Room temperature cabbage leaves versus hot water bag	1	63	Mean Difference (IV, Fixed, 95% CI)	-1.16 [-1.36, -0.96]
1.3.2 Cabbage leaf extract versus placebo cream	1	39	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.18, 0.58]
1.4 Maternal opinion of treatment: women satisfied or very satisfied	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.4.1 Cold cabbage leaves versus routine care	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.4.2 Cold cabbage leaves versus cold gel packs	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.5 Cessation of breastfeeding before six months	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.5.1 Cold cabbage leaves versus routine care	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.5.2 Cold cabbage leaves versus cold gel packs	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

**Analysis 1.1. Comparison 1: Cabbage leaf treatments versus other treatments/
placebo, Outcome 1: Breast pain (0-10 VAS; higher score = more pain)**

**Analysis 1.2. Comparison 1: Cabbage leaf treatments versus other treatments/
placebo, Outcome 2: Breast hardness (higher score = more hardness)**

Analysis 1.3. Comparison 1: Cabbage leaf treatments versus other treatments/ placebo, Outcome 3: Breast engorgement (measured with 6-point engorgement scale)

Analysis 1.4. Comparison 1: Cabbage leaf treatments versus other treatments/ placebo, Outcome 4: Maternal opinion of treatment: women satisfied or very satisfied

Analysis 1.5. Comparison 1: Cabbage leaf treatments versus other treatments/placebo, Outcome 5: Cessation of breastfeeding before six months

Comparison 2. Compress treatments versus other treatments/routine care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Breast pain (higher score = more pain)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1.1 Herbal compress versus hot compress	1	500	Mean Difference (IV, Fixed, 95% CI)	-1.80 [-2.07, -1.53]
2.1.2 Cactus & aloe cold compress versus massage therapy	1	102	Mean Difference (IV, Fixed, 95% CI)	0.17 [-0.55, 0.89]
2.1.3 Cactus & aloe cold compress plus massage versus massage alone	1	100	Mean Difference (IV, Fixed, 95% CI)	-1.27 [-1.75, -0.79]
2.2 Number of women with moderate or severe breast induration/hardness	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.2.1 Cactus & aloe cold compress versus massage therapy	1	102	Risk Ratio (M-H, Fixed, 95% CI)	0.66 [0.51, 0.87]
2.2.2 Cactus & aloe cold compress plus massage versus massage alone	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.25, 0.58]
2.3 Breast engorgement (higher score = more pain)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.3.1 Hollyhock leaf compress versus warm compress	1	40	Mean Difference (IV, Fixed, 95% CI)	-2.82 [-4.60, -1.04]
2.4 Cessation of breastfeeding	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.4.1 Cactus & aloe cold compress versus massage therapy	1	102	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.45, 2.58]
2.4.2 Cactus & aloe cold compress plus massage versus massage alone	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.06, 1.12]
2.5 Number of women with adverse effects	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.5.1 Herbal compress versus hot compress	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 2.1. Comparison 2: Compress treatments versus other treatments/ routine care, Outcome 1: Breast pain (higher score = more pain)

Analysis 2.2. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 2: Number of women with moderate or severe breast induration/hardness

Analysis 2.3. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 3: Breast engorgement (higher score = more pain)

Analysis 2.4. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 4: Cessation of breastfeeding

Analysis 2.5. Comparison 2: Compress treatments versus other treatments/routine care, Outcome 5: Number of women with adverse effects

Comparison 3. Medical treatment versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Breast swelling (no improvement)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1.1 Protease complex versus placebo	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.15, 0.79]
3.1.2 Serrapeptase versus placebo	1	70	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.36, 1.55]
3.2 Breast engorgement (symptoms not subsided after three days of treatment)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.2.1 Oxytocin versus placebo	1	45	Risk Ratio (M-H, Fixed, 95% CI)	3.12 [0.68, 14.44]
3.2.2 Serrapeptase versus placebo	1	70	Risk Ratio (M-H, Fixed, 95% CI)	0.36 [0.14, 0.88]
3.3 Breast pain (no improvement)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.3.1 Protease complex versus placebo	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.04, 0.74]
3.3.2 Serrapeptase versus placebo	1	70	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.21, 1.49]

Analysis 3.1. Comparison 3: Medical treatment versus placebo, Outcome 1: Breast swelling (no improvement)

Analysis 3.2. Comparison 3: Medical treatment versus placebo, Outcome 2: Breast engorgement (symptoms not subsided after three days of treatment)

Analysis 3.3. Comparison 3: Medical treatment versus placebo, Outcome 3: Breast pain (no improvement)

Comparison 4. Cold gel packs versus routine care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Breast pain (higher score = more pain)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.2 Breast hardness (higher score = more hardness)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.3 Maternal opinion of treatment: women satisfied or very satisfied	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4.4 Cessation of breastfeeding before six months	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 4.1. Comparison 4: Cold gel packs versus routine care, Outcome 1: Breast pain (higher score = more pain)

Analysis 4.2. Comparison 4: Cold gel packs versus routine care, Outcome 2: Breast hardness (higher score = more hardness)

Analysis 4.3. Comparison 4: Cold gel packs versus routine care, Outcome 3: Maternal opinion of treatment: women satisfied or very satisfied

Analysis 4.4. Comparison 4: Cold gel packs versus routine care, Outcome 4: Cessation of breastfeeding before six months

Comparison 5. Massage-based therapies versus other treatments/routine care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Breast pain (higher score = more pain)	1	102	Mean Difference (IV, Fixed, 95% CI)	-1.44 [-2.14, -0.74]
5.2 Number of women with moderate or severe breast induration/hardness	1	102	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.36, 0.92]
5.3 Cessation of breastfeeding	1	102	Risk Ratio (M-H, Fixed, 95% CI)	0.23 [0.05, 1.02]

Analysis 5.1. Comparison 5: Massage-based therapies versus other treatments/routine care, Outcome 1: Breast pain (higher score = more pain)

Analysis 5.2. Comparison 5: Massage-based therapies versus other treatments/routine care, Outcome 2: Number of women with moderate or severe breast induration/hardness

Analysis 5.3. Comparison 5: Massage-based therapies versus other treatments/routine care, Outcome 3: Cessation of breastfeeding

Comparison 6. Other treatments versus other treatments/advice/routine care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Breast pain (0-10 VAS; higher score = more pain)	1	54	Mean Difference (IV, Fixed, 95% CI)	-2.01 [-2.60, -1.42]
6.1.1 Gua-Sha therapy versus hot packs and massage	1	54	Mean Difference (IV, Fixed, 95% CI)	-2.01 [-2.60, -1.42]
6.2 Breast engorgement (0-10 VAS; higher score = more pain)	1	54	Mean Difference (IV, Random, 95% CI)	-2.42 [-2.98, -1.86]
6.2.1 Gua-Sha therapy versus hot packs and massage	1	54	Mean Difference (IV, Random, 95% CI)	-2.42 [-2.98, -1.86]
6.3 Breast engorgement	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.47, 1.10]
6.3.1 Acupuncture versus routine care	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.47, 1.10]
6.4 Cessation of breastfeeding within 6 weeks	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.17, 1.49]
6.4.1 Acupuncture versus routine care	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.17, 1.49]
6.5 Pyrexia	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.72, 0.94]
6.5.1 Acupuncture versus routine care	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.72, 0.94]
6.6 Breast abscess	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.04, 1.01]
6.6.1 Acupuncture versus routine care	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.04, 1.01]

Analysis 6.1. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 1: Breast pain (0-10 VAS; higher score = more pain)

Analysis 6.2. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 2: Breast engorgement (0-10 VAS; higher score = more pain)

Footnotes

(1) Breast Engorgement Scale based on VAS (0-10)) with higher scores relating to greater degree of engorgement

Analysis 6.3. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 3: Breast engorgement

Footnotes

(1) Combined measurement of breast erythema, tension and pain

**Analysis 6.4. Comparison 6: Other treatments versus other treatments/
advice/routine care, Outcome 4: Cessation of breastfeeding within 6 weeks**

Analysis 6.5. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 5: Pyrexia

Analysis 6.6. Comparison 6: Other treatments versus other treatments/advice/routine care, Outcome 6: Breast abscess

Comparison 7. Ultrasound versus sham ultrasound

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Analgesic requirement	1	45	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.63, 1.51]

Analysis 7.1. Comparison 7: Ultrasound versus sham ultrasound, Outcome 1: Analgesic requirement

APPENDICES

Appendix 1. Search methods for ICTRP and ClinicalTrials.gov

ICTRP

(searched with all synonyms)

breast AND engorgement

ClinicalTrials.gov

Advanced search

Breast engorgement

WHAT'S NEW

Date	Event	Description
2 October 2019	New citation required but conclusions have not changed	Data from eight new studies added, but conclusions remain unchanged as none of the data could be pooled in meta-analysis.
2 October 2019	New search has been performed	Search updated and eight new trials added to review.

HISTORY

Protocol first published: Issue 1, 2008

Review first published: Issue 9, 2010

Date	Event	Description
1 July 2016	Amended	Corrected typographical error and updated affiliation for Contact person.
30 June 2015	New search has been performed	Search updated. Five new trials included (Ahmadi 2011; Batista 2014; Chiu 2010; Kee 1989; Roberts 1998). One of these was previously excluded (Kee 1989) and one that was in 'Awaiting classification' has been included (Roberts 1998). Methods updated, four new outcomes added and the background has been revised. A 'Summary of findings' table has been added.
30 June 2015	New citation required but conclusions have not changed	Five new trials included, the conclusions remain unchanged.
23 September 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Irena Zakarija-Grkovic and Fiona Stewart independently assessed study eligibility and carried out data extraction and assessment of risk of bias. The two review authors equally contributed to the update of this review.

DECLARATIONS OF INTEREST

Irena Zakarija-Grkovic: Irena is an International Board Certified Lactation Consultant, member of the Academy of Breastfeeding Medicine and a member of the International Advisory Council of the World Alliance for Breastfeeding Action.

Fiona Stewart: none.

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Internal sources

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External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We added in an additional search of [ClinicalTrials.gov](https://clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP).

The protocol [Methods](#) section was updated for the 2016 update. The following outcomes, which were not in the original protocol, were added to the 2016 update because they had not been adequately addressed in the earlier version of the review, and were felt to be important for women with breast engorgement.

Primary outcomes: breast pain, breast induration/hardness, breast swelling, breast engorgement.

Secondary outcome: pyrexia (as defined by trial authors) was added to replace temperature higher than 38 degrees celsius.

Methods for GRADE assessment of the certainty of the evidence were added for the 2016 update and a 'Summary of findings' table was incorporated.

For the 2019 update, "treatment adverse events" were added to the secondary outcomes in line with latest Cochrane guidelines; whereas, "maternal acceptance of treatment" was deleted from the list of secondary outcomes because it was felt that this was adequately covered by the outcome "maternal opinion of treatment".

We were unable to investigate subgroup analysis and assessment of heterogeneity. The relatively small number of included studies with diverse interventions prevented us from carrying out meaningful sensitivity analysis.

For this version of the review, we did not identify any cluster-randomised trials.

NOTES

This review was not updated earlier due to scarce availability of new evidence; hence, conducting a review earlier may have been unnecessary and wasteful.

INDEX TERMS

Medical Subject Headings (MeSH)

Acupuncture Therapy; Brassica; Breast Diseases [etiology] [*therapy]; Cryotherapy [methods]; Lactation Disorders [*therapy]; Massage; Mastodynia [therapy]; Oxytocin [therapeutic use]; Peptide Hydrolases [therapeutic use]; Phytotherapy [methods]; Plant Leaves; Randomized Controlled Trials as Topic; Ultrasonic Therapy [methods]

MeSH check words

Female; Humans; Pregnancy