# 文獻查證

## 2018年2月13日


吳佳臻
醫師

陳惠娟
專科護理師

陳婉亭
實習醫學生

# 臨床場景

3480克健康新生兒
先生想問老婆吃甚麼奶水才會比較多？多喝魚湯吃豬腳燉花生有用嗎？怕老婆奶塞住、乳腺炎，用舒乳棒、或請舒乳師來按摩、通奶有效嗎？需需要先買卵磷脂(Lecithin)來吃？
母親有沒有與寶寶同室是否影響寶寶吃母奶？
寶寶吃奶嘴是否影響後續吸母奶？

## 爸爸的疑問:

1. 喝魚湯、吃豬腳燉花生是否能增進產後婦女奶水分泌？
2. 舒乳棒、按摩、通奶是否能預防產後乳腺炎？
3. 產後母親食用卵磷脂(Lecithin)是否能增進奶水分泌？
4. 母親有沒有與寶寶同室是否影響寶寶吃母奶？
5. 寶寶吃奶嘴是否影響後續吸母奶？

## 病人的治療考量:

1. 希望奶水分泌多一點，但不希望奶水塞住
2. 產後疲憊，但不希望影響寶寶吸奶

*The EBM process :*

# STEP 1 :

**Ask a clinical question in PICO format**

# 臨床場景→形成PICO

Ask 問題

PICO -1

治療型問題

| | 關鍵字 | 英文 | 同義字/Mesh/EMtree |
|---|---|---|---|
| P | 產後婦女 | Postpartum women | Puerperium/Period, Postpartum |
| I | 食用卵磷脂 | Lecithin | |
| C | 沒有食用卵磷脂/其他民俗療法 | placebo | Alternative therapy |
| O | 奶水分泌 | Milk secretion | |

# 關鍵字

選擇此PICO原因
病人較關心；臨床上重要；且容易遇到的問題

Ask 問題

PICO -2

治療型問題

| | 關鍵字 | 英文 | 同義字 /Mesh/EMtree |
|---|---|---|---|
| P | 新生兒 | Newborn | Infant, baby |
| I | 有限制使用奶嘴 | Restricted pacifier use | pacifiers |
| C | 有限制使用奶嘴 | Not restricted pacifier use | placebo |
| O | 哺乳時間<br>哺乳困難<br>寶寶健康 | Breastfeeding duration<br>Breasting difficulties<br>Infant health | Feeding time, Breast Breastfeeding time |

# 搜索策略-提升檢索效率

Acquire 檢索

- 運用布林邏輯 ，先以P、I搜尋，再依結果適當加入關鍵字。

| P | And | I | And | C | And | O |
|---|---|---|---|---|---|---|
| Newborn OR Infant | | Restricted pacifier use | | Not restricted pacifier use | | Breastfeeding duration OR Breastfeeding difficulties |

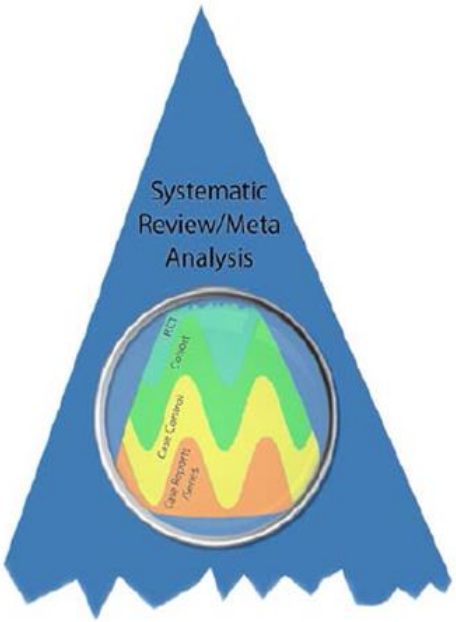
| 限定搜尋範圍 | Free full text、Within 5 years、Human species |
|---|---|
| 限定研究類型 | Systematic review、Meta-analysis、Randomized controlled trial |
| 限定語言地區 | English、中文[台灣本土文獻] |

# STEP 2 :

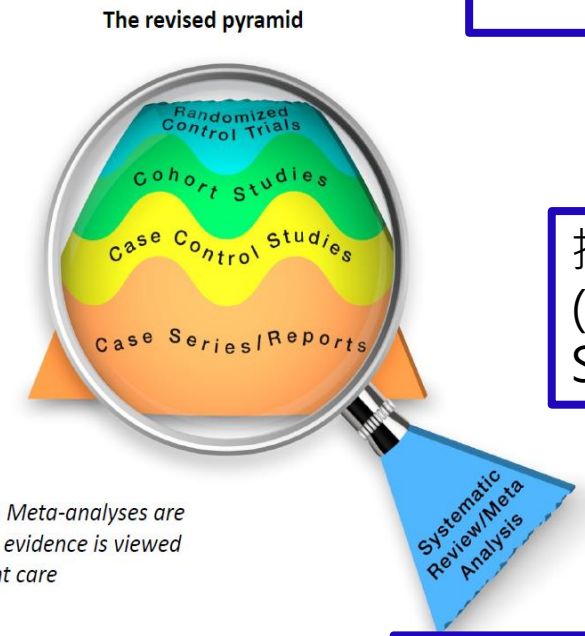
## Search for the most relevant best evidence

# 搜索策略

Acquire
檢索




natic reviews & Meta-analyses are
through which evidence is viewed
pplied to patient care




前景型問題 (治療型)*

搜尋 Level 1證據
(Synopses of SR of RCT or SR of RCT or n-1 trial)

尋獲

未尋獲

搜尋該SR未收錄、更新的Level 2證據
(Synopses of RCT or RCT)

搜尋 Level 2 證據
(Synopses of RCT or RCT)

# 搜索策略

Acquire
檢索

Clinical Queries

Systematic Review(Meta-analysis)→ RCT → Cohort study

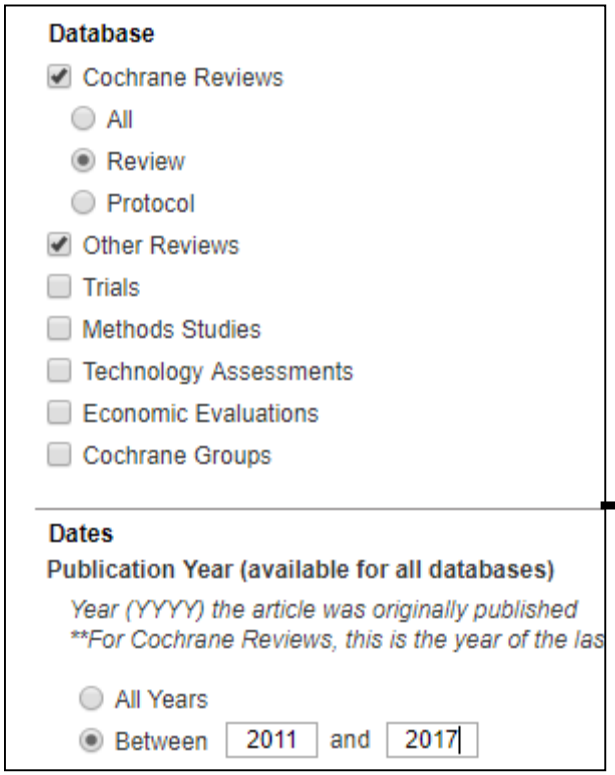
With in 5 years

Meet our **PICO**

# 搜索Cochrane Library-提升檢索效率

Acquire
檢索


先從二級資料庫開始搜尋，之後才進入一級資料庫




Newborn breast feeding: pacifier and placebo

↓

輸入關鍵字、適當使用**Truncation及Boolin**

『 breast feeding* newborn pacifier and placebo*』

→

使用Limit功能

**限定『Review』文章**

**限定『2012-2018』文章**

# 搜索Embase-提升檢索效率

Acquire
檢索

輸入關鍵字、適當使用**Truncation及Boolin**
『 breast feeding* newborn
pacifier and placebo*』

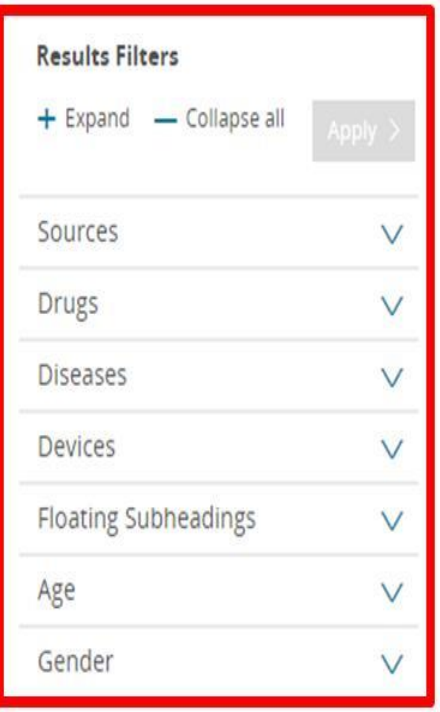

使用EBM Limit功能
**限定『Review』文章**
**限定『2012-2018』文章**

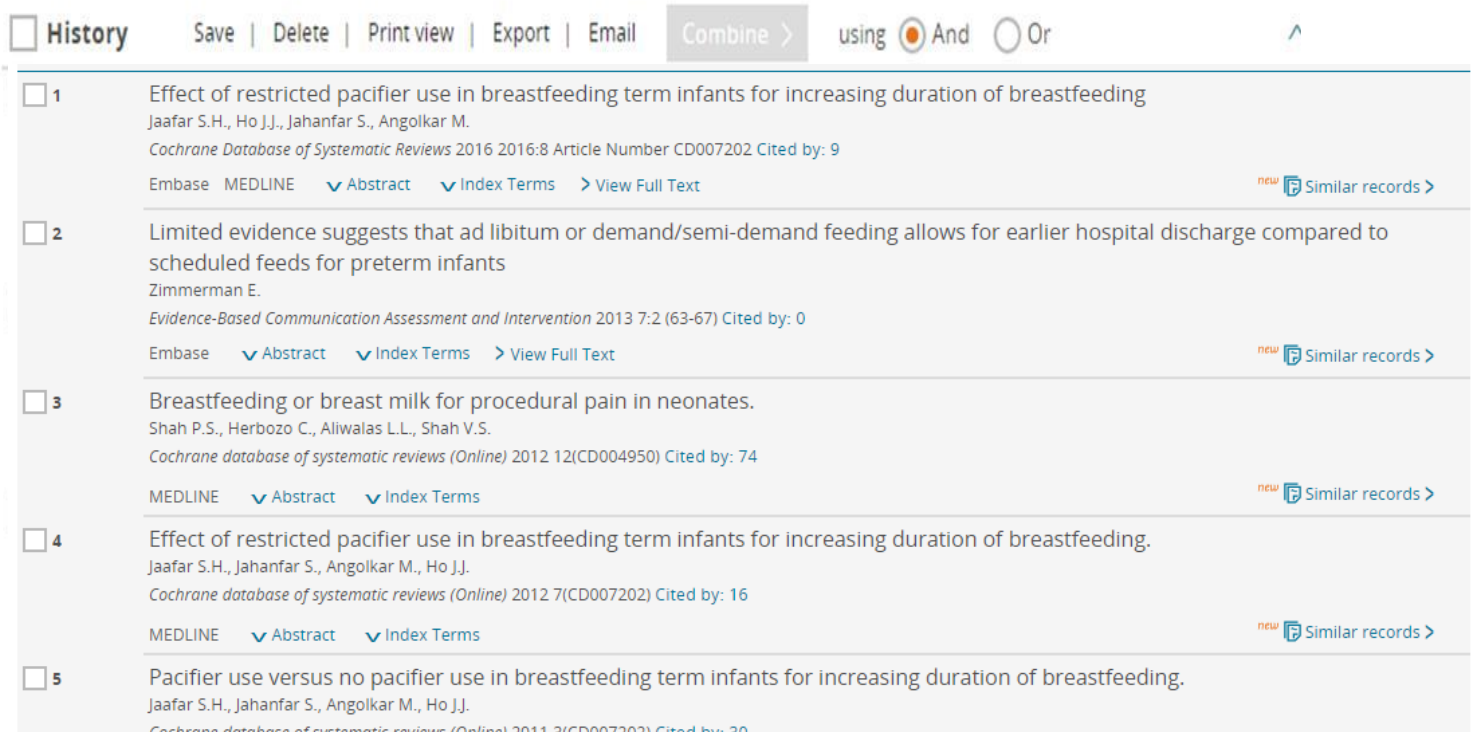
# 使用 Filter 及 Limit


## Filter功能

| | |
|---|---|
| EBM | SR RCT |
| SOURCES | 刪除與PuMed重複文獻 |
| Aged | 限制新生兒 |
| Date | 限制5年內 |
| Animal | 限制Human |

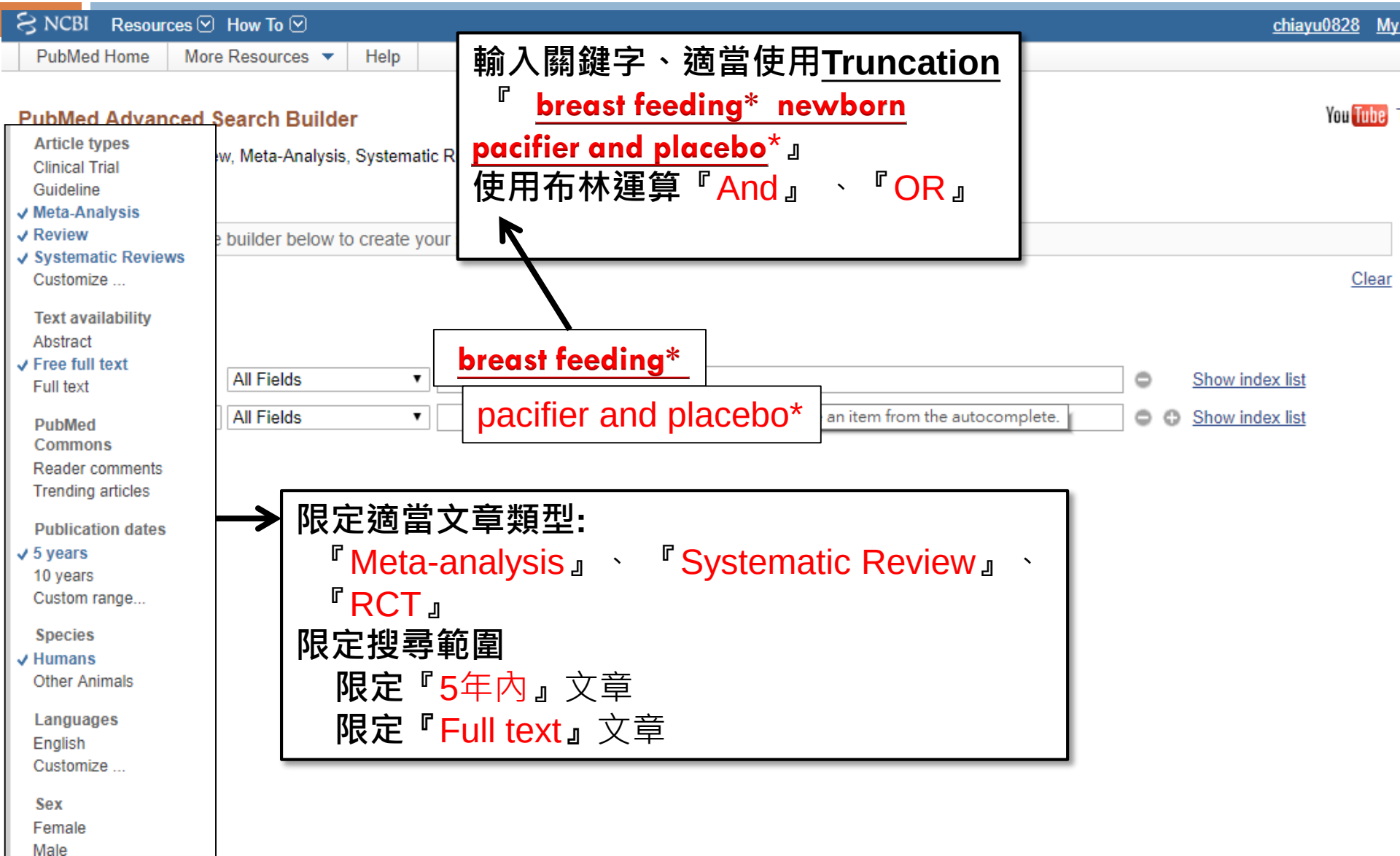
Acquire 檢索



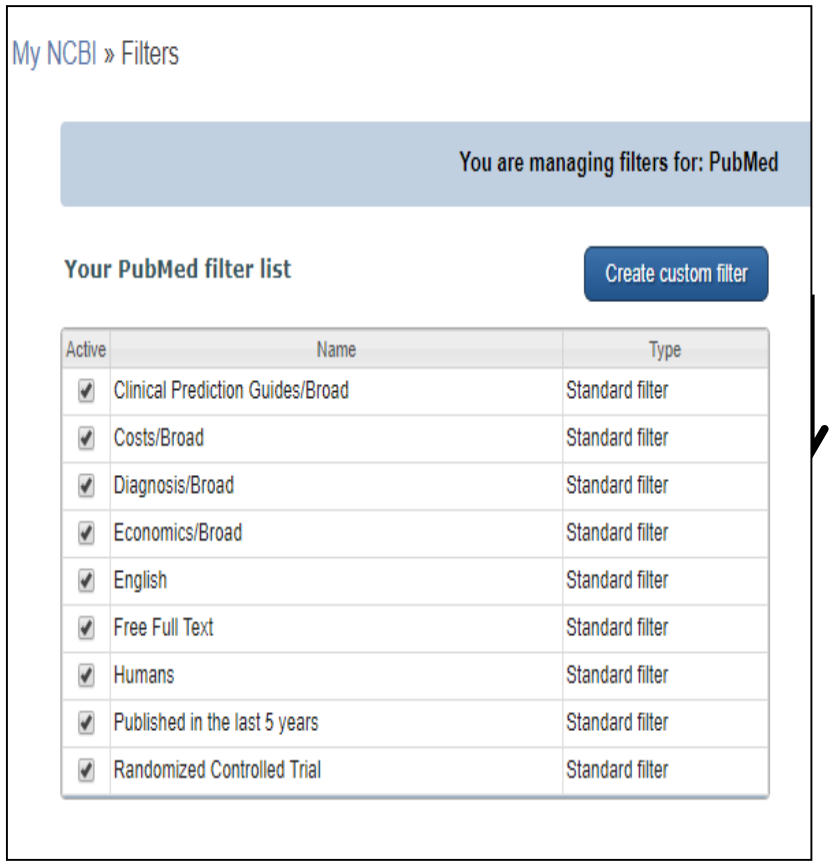
# 搜索Pubmed-利用限定縮小範圍

Acquire
檢索



# 搜索Pubmed-
# 利用My NCBI篩選器提升效率

Acquire
檢索


My NCBI » Filters

You are managing filters for: PubMed

Your PubMed filter list

Create custom filter

| Active | Name | Type |
|---|---|---|
| ☑ | Clinical Prediction Guides/Broad | Standard filter |
| ☑ | Costs/Broad | Standard filter |
| ☑ | Diagnosis/Broad | Standard filter |
| ☑ | Economics/Broad | Standard filter |
| ☑ | English | Standard filter |
| ☑ | Free Full Text | Standard filter |
| ☑ | Humans | Standard filter |
| ☑ | Published in the last 5 years | Standard filter |
| ☑ | Randomized Controlled Trial | Standard filter |

**根據臨床問題類型篩選**

『治療型問題』

『診斷型問題』

『預後型問題』

『病因型問題』

**納入含有經濟效益分析的文章**

『Costs/broad』『Economics/broad』

**找出包含亞洲族群的文章**

『Chinese』

# 搜索華藝--不遺漏重要亞洲文獻

airiti Library 華藝線上圖書館

Language

國軍醫院聯合圖書館-國防醫學院，您好！

瀏覽 進階檢索 儲值&購物車 登入 | 加入會員 | 購買點數 | 個人化服務 | 客服中心 | 使用說明 | 網站地圖

| 文章 | 出版品 | 奶嘴 哺乳時間 嬰兒 更多選項 查詢歷史

期刊文章 6 | 會議論文 0 | 碩博士論文 2 | 電子書 1 | 紙本書 233

依下方條件來精確結果

來源資料庫

CEPS中文電子期刊 (2)
CJTD中國大陸期刊 (4)

學科分類

醫藥衛生（原：醫學與生命科學） (6)

年代

2016年以後 (1)
2014年以後 (2)
2012年以後 (3)

▼ 展開

查詢 (新生兒 奶嘴 哺乳) = 所有欄位

篇名.關鍵字.摘要 | 作者 | 刊名 | 起始年 – 結束年 | 檢索結果再查詢

每頁 10 筆

共 6 筆 ， 1 - 6 筆

共 1 頁 1

書目匯出 加入追蹤 加入購物車 相關程度最高

1 新生兒使用安撫奶嘴是否會降低哺餵母乳持續性

賴寶琴 ； 曾婉怡 ；

彰化護理 23卷4期 ( 2016/12) , 51-54

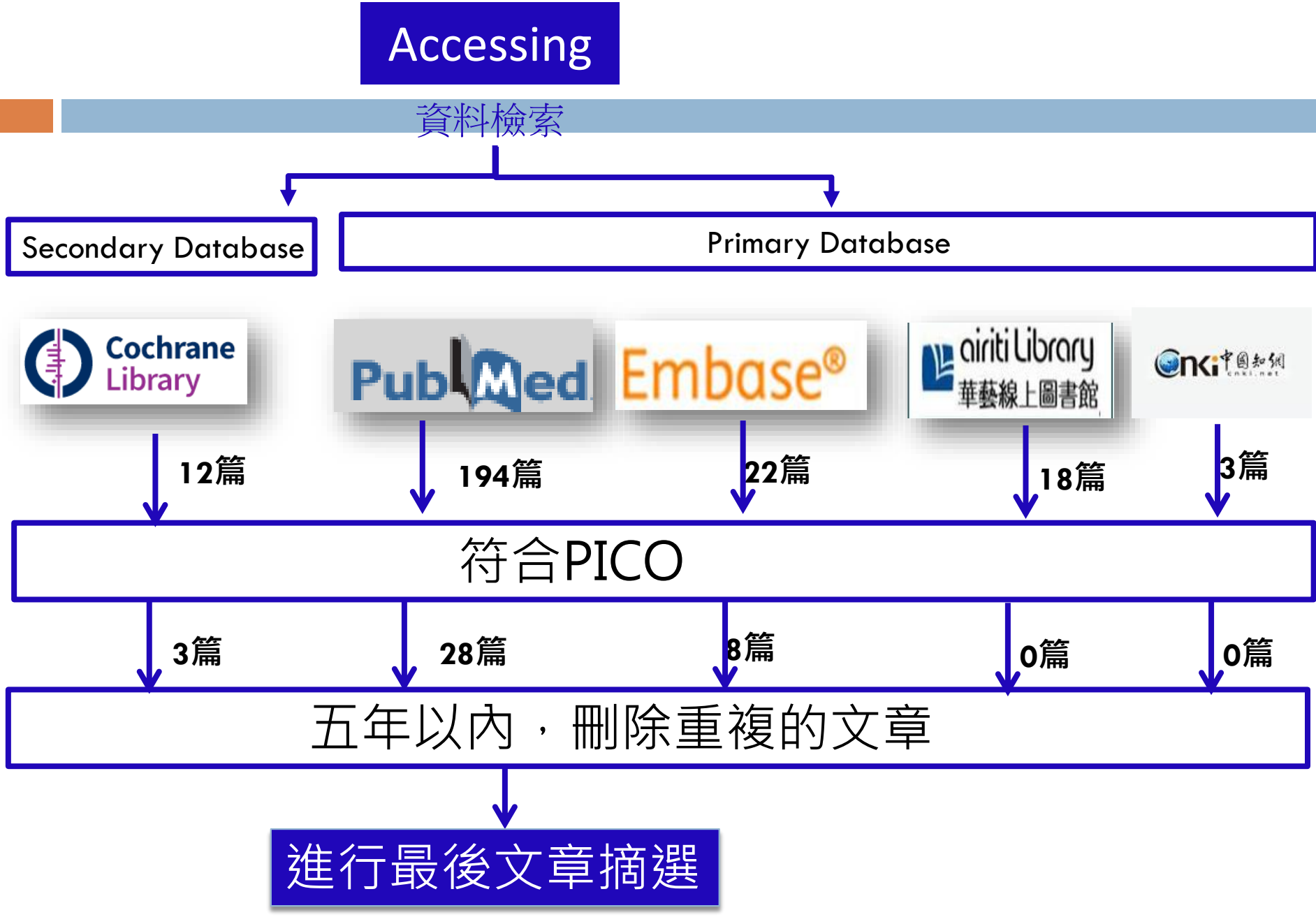
infant ； pacifier ； breastfeeding ； 新生兒 ； 安撫奶嘴 ； 哺餵母乳 ；

10.6647/CN.23.04.07

# 搜尋中國知網Cnki-不遺漏重要亞洲文獻

# Accessing

## 資料檢索



# 篩選結果-選出最佳文獻

Acquire
檢索

| | 文章 | M | P | I | C | O |
|---|---|---|---|---|---|---|
| Cochrane Library | 〔2016〕〔2012〕Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding | ● | ● | ● | ● | ● |
| | 〔 2011〕Pacifier use compared with no pacifier use in breastfeeding term infants for increasing duration of breastfeeding | ● | ● | ● | ● | ● |
| NHS National Institute for Health Research | 〔 2011〕Pacifier use versus no pacifier use in breastfeeding term infants for increasing duration of breastfeeding. | ● | ● | ● | ● | ● |
| NHS National Institute for Health Research | 〔2008〕Breastfeeding promotion for infants in neonatal units: A systematic review and economic analysis | ● | ● | ● | ● | ● |
| JAMA Pediatrics | 〔2009〕Pacifiers and breastfeeding: A systematic review | ● | ● | ● | ● | ● |

# 嚴格評讀

Appraisal
評讀

Cochrane Database of Systematic Reviews

## Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

New search | Review | Intervention

Sharifah Halimah Jaafar, Jacqueline J Ho, Shayesteh Jahanfar, Mubashir Angolkar

First published: 30 August 2016

Editorial Group: Cochrane Pregnancy and Childbirth Group

DOI: 10.1002/14651858.CD007202.pub4 View/save citation

Cited by (CrossRef): 5 articles Check for updates | Citation tools

## 選擇原因

- 來源為次級資料庫
- 最符合臨床問題
- 最佳的研究設計
- 有全文可供評讀
- 期刊本身有代表性

CASP Systematic Review Checklist

# STEP 3 :

## Critical appraise the evidence

# 1.是否問了一個明確的臨床問題?

評讀
Validity

◯Yes ◯No ◯Unclear

## OBJECTIVES

I、C

To assess the effect of restricted pacifier use versus unrestricted pacifier use in healthy full-term newborns whose mothers have initiated breastfeeding and intend to exclusively breastfeed, on the duration of breastfeeding, other breastfeeding outcomes and infant health.

P

O

作者清楚地說明了PICOT，因此評讀結果為Yes

# 2.是否收納適當的研究類型?

Appraisal
評讀

**Types of studies**

All randomised controlled trials including quasi-randomised trials and cluster-randomised trials. Cross-over trials were not eligible for inclusion.

**Types of participants**

Healthy full-term newborns whose mothers have initiated breast-feeding and intend to exclusively breastfeed regardless of whether they were born at home or in hospital. We planned to exclude studies including newborns exposed to bottle feeding prior to en-rolment.

**Types of interventions**

Advice against pacifier use (restricted) compared with unrestricted or actively encouraged use of a pacifier in breastfeeding infants from postpartum period till six months of age.

優點

1.收入符合治療型問題的，收錄2篇RCT的文章

2.清楚定義納入及排除條件

3. 納入的RCT，皆使用雙盲

4.多中心RCT 文章是為雙盲試驗。

5.純RCT文章分析統計

# 2.是否收納適當的研究類型?

Appraisal
評讀

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

Jenik 2009

| | |
|---|---|
| Methods | A multicentre, non-inferiority, RCT. The randomisation was carried out centrally with consecutively numbered, sealed, opaque envelopes containing random-generated numbers constructed by an independent statistician |
| Participants | 1021 mothers highly motivated to breastfeed their term newborns of birthweight 2500 g or more and who regained weight by 15 days postpartum, were assigned to offer or not to offer pacifiers as part of the advice given on how to comfort crying infants. Mothers with breast problems that could interfere with breastfeeding were not included in the study. The study did not state whether twins were included |

Kramer 2001

| | |
|---|---|
| Methods | Double-blinded RCT. |
| Participants | A total of 281 healthy breastfeeding women who were motivated to breastfeed and their healthy term singleton infants recruited in the immediate postpartum period prior to hospital discharge |
| Interventions | Participants were randomly allocated to 1 of 2 counselling interventions provided by a research nurse trained in lactation counselling. A basic breastfeeding promotion package was included in both the intervention and control groups<br>The intervention group (n = 140) were "asked to avoid pacifiers when the infant cried or fussed" and suggested alternative ways to provide comfort<br>The control group (n = 141) "all options were discussed for calming an infant" including pacifier use |
| Outcomes | Mothers were asked to complete a validated behaviour diary on 3 consecutive days, at 4, 6 and 9 weeks of age. Study mothers were interviewed at 3 months<br>Primary outcome measures: rate of early weaning at 3 months, 72-hour infant behaviour logs detailing frequency and duration of crying and fussing and pacifier use at 4, 6, 9 weeks |
| Notes | The trial was carried out from January 1998 to August 1999 on women giving birth at the Royal Victoria Hospital, a McGill University-affiliatted maternity hospital in Montreal, |

# 2.是否收納適當的研究類型?

Appraisal 評讀

○Yes ○No ○Unclear

**Included studies**

*See* Characteristics of included studies. We included three studies involving 1915 babies (Jenik 2009; Kramer 2001; Schubiger 1997). However, only two of these studies (involving 1302 babies: Jenik 2009; Kramer 2001) contribute data to the analyses.

Jenik 2009: a multicentre trial evaluated pacifier use in breastfeeding infants once lactation was well-established to see whether it reduced the prevalence or duration of breastfeeding. A total of 1021 mothers highly motivated to breastfeed were recruited and randomly assigned to whether pacifier was offered (n = 528) or not offered (n = 493). The study was designed as a non-inferiority trial and only mothers who were already successfully breastfeeding at two weeks and who indicated their intention to continue to do so for at least three months were enrolled. Mothers with breast problems that could interfere with breastfeeding (sore nipples, mastitis, inverted nipples, breast surgery) were not included. Participating mothers were interviewed at one, two, three, four, five, six, eight, 10 and 12 months after birth or until breastfeeding ended. Interviews were conducted by a research assistant using a structured questionnaire designed to assess exclusive or any breastfeeding prevalence, duration of breastfeeding and whether the baby had used a pacifier. The primary outcome was prevalence of exclusive breastfeeding at three months. The main secondary outcomes were the prevalence of exclusive and any breastfeeding and duration of any breastfeeding. Primary analysis was by intention-to-treat. Comparison between the two groups in the study did not show any difference in the baseline characteristics namely

| | |
|---|---|
| **P** | mothers who were already successfully breastfeeding at two weeks and who indicated their intention to continue to do so for at least three months were enrolled |
| I | baby had used a pacifier |
| C | baby had NOT used a pacifier |
| O | breastfeeding prevalence, duration of breastfeeding |
| T | interviewed at one, two, three, four,five, six, eight, 10 and 12 months after birth or until breastfeeding ended. |

# 3.有無遺漏重要相關研究?

Appraisal 評讀

◯Yes ✓ ◯No ◯Unclear

**Electronic se Electronic searches**

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting their Information Specialist (30 June 2016).

The Register is a database containing over 22,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate the Pregnancy and Childbirth Group'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 to the editorial information about the Cochrane Pregnancy and Childbirth Group in the Cochrane Library and select the '*Specialized Register*' section from the options on the left side of the screen.

Briefly, the Cochrane Pregnancy and Childbirth Group'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

**Searching other resources**

We searched the reference lists of retrieved studies.
We did not apply any language or date restrictions.

優點

1.作者搜尋了重要一級和二級資料庫。

- Cochrane Pregnancy and Childbirth Group's Trials Register by contacting their Information Specialist (30 June 2016).
- CENTRAL,MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service
- – 搜尋註冊但尚未發表的試驗

– conference proceedings

– previous SR

2. 清楚說明納入及排除理由。

3.沒有研究設計限制，沒有語言搜尋限制。

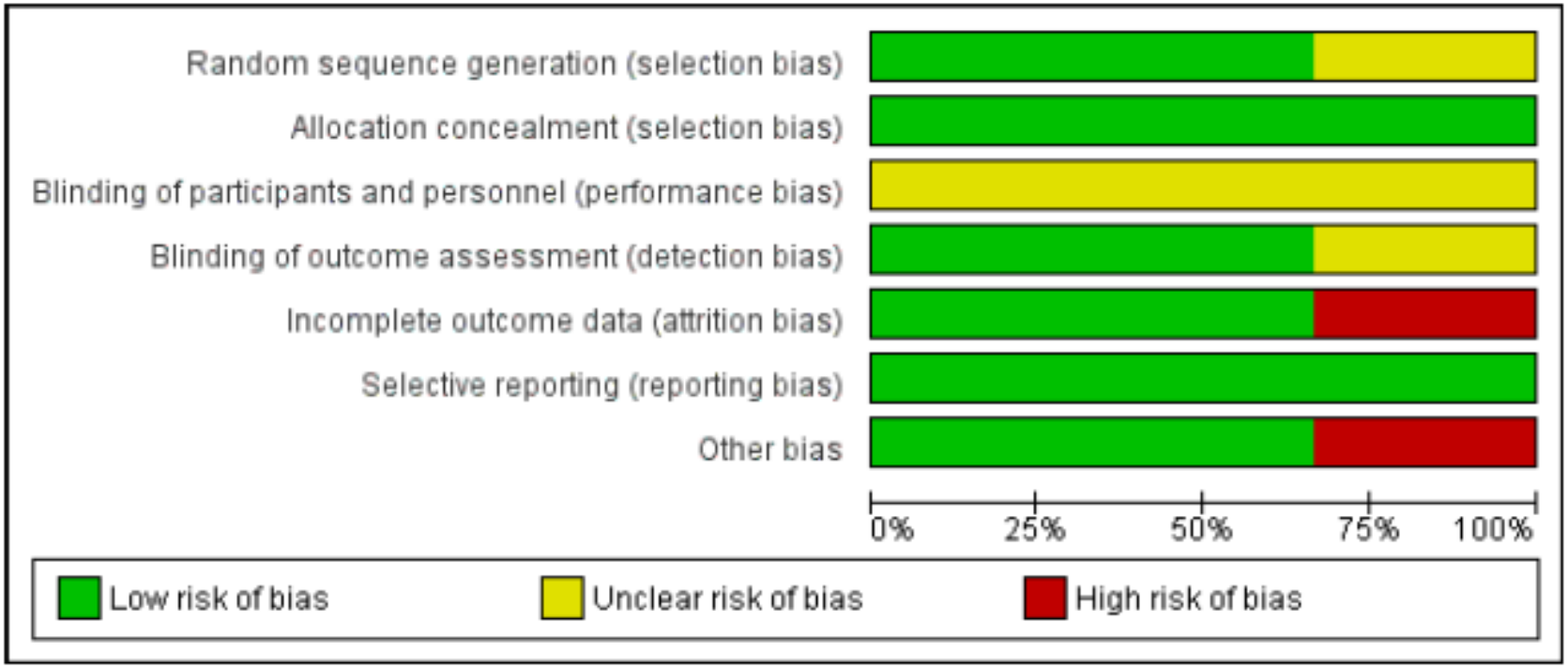
4.文章收集至2016年6月30日。

# 4.是否評估收納研究品質?

Appraisal
評讀

Assessment of Risk of bias in included studies （2 Authors）
Cochrane Handbook for Systematic Reviews of Interventions

**Figure 1. : 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**



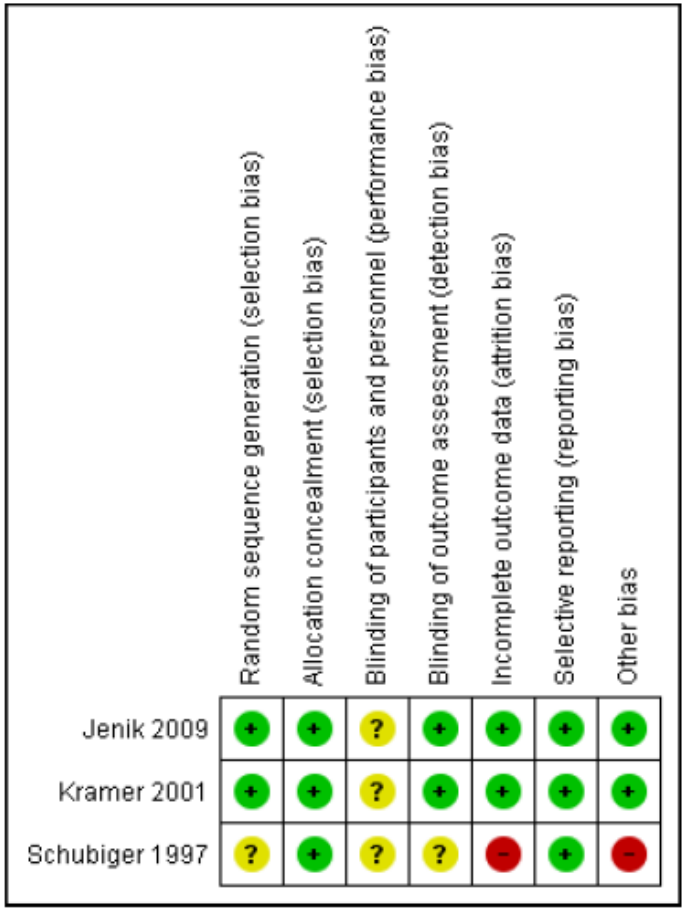

**整體BIAS: 低**

# 4.是否評估收納研究品質?

Appraisal
評讀

Assessment of Risk of bias in included studies （2 Authors）
Cochrane Handbook for Systematic Reviews of Interventions

**Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.**




**整體BIAS: 低**

# 4.是否評估收納研究品質?

Appraisal
評讀

**Assessment of risk of bias in included studies**

In the previous version of this review (Jaafar 2012), two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Any disagreement was resolved by discussion or by involving a third assessor.

1. Random sequence generation (checking for possible selection bias)
2. Allocation concealment (checking for possible selection bias)
3-1. Blinding of participants and personnel (checking for possible performance bias)
3-2. Blinding of outcome assessment (checking for possible detection bias)
4. Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)
5. Selective reporting (checking for reporting bias)
6. Other bias (checking for bias due to problems not covered by (1) to (5) above)
7. Overall risk of bias

優點

1.由兩位作者獨立評讀。

2.使用Cochrane Handbook for Systematic Reviews of Interventions評估文章品質。

3.將各種不同bias分項評估

4.內文對於各項的結果皆有清楚的定義。

5 於文章內文中有將重要bias及limitation探討.

# 4.是否評估收納研究品質?

Yes ○No ○Unclear

Appraisal 評讀

**Assessment of the quality of the evidence using the GRADE approach**

For this update (2016) the quality of the evidence was assessed using the GRADE approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence relating to the following outcomes for the main comparisons of unrestricted pacifier versus no pacifier use in breastfeeding infants.

Primary outcomes

1. Prevalence or proportion of infants fully breastfed four to six months of age.
2. Duration of full or exclusive breastfeeding (months).

Secondary outcomes

1. Breastfeeding difficulties such as cracked nipples, breast engorgement, mastitis.
2. Maternal satisfaction and level of confidence in parenting.
3. Infant otitis media.
4. Infant dental malocclusion.

We used GRADEpro Guideline Development Tool to import data from Review Manager 5.3 (RevMan 2014) in order to create a 'Summary of findings' table. A summary of the intervention effect and a measure of quality for each of the above outcomes was produced using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' 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.

1.使用Grade approach評估文章證據品質

# 5.結果是否合併?是否合理?

Appraisal
評讀

## Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau², I² and Chi² statistics. We regarded heterogeneity as substantial if an I² was greater than 30% and either the Tau² was greater than zero, or there was a low P value (less than 0.10) in the Chi² test for heterogeneity. Had we identified substantial heterogeneity (above 30%), we planned to explore it by pre-specified subgroup analysis.

We carried out statistical analysis using the Review Manager software (RevMan 2014). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar.

If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we planned to use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. The random-effects summary would have been treated as the average of the range of possible treatment effects and we would have discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we planned not to combine trials. If we had used random-effects analyses, the results would have been presented as the average treatment effect with 95% confidence intervals, and the

## Subgroup analysis and investigation of heterogeneity

Had we identified substantial heterogeneity, we would have investigated it using subgroup analyses and sensitivity analyses. We would have considered whether an overall summary was meaningful, and if it was, we would have used random-effects analysis to produce it.

We planned to carry out the following subgroup analyses:

1. primiparous versus multiparous mother;
2. vaginal delivery versus cesarean section.

We planned to use the following outcomes in subgroup analyses:

1. duration of full breastfeeding (months);
2. duration of any or partial breastfeeding (months);
3. prevalence or proportion of infants being fully or partially breastfed at three, four and six months of age.

However, we were unable to carry out subgroup analysis in this update due to lack of data.

In future updates, if subgroup analysis is possible, we will assess subgroup differences by interaction tests available within RevMan (RevMan 2014). We will report the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I² value.

## Sensitivity analysis

We planned to carry out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, high attrition rates, or both, with poor quality studies being excluded from the analyses in order to assess whether this makes any difference to the overall result. However, we were unable to carry out sensitivity analysis due to lack of data in this update.

# 5.結果是否合併?是否合理?

Yes ○No ○Unclear

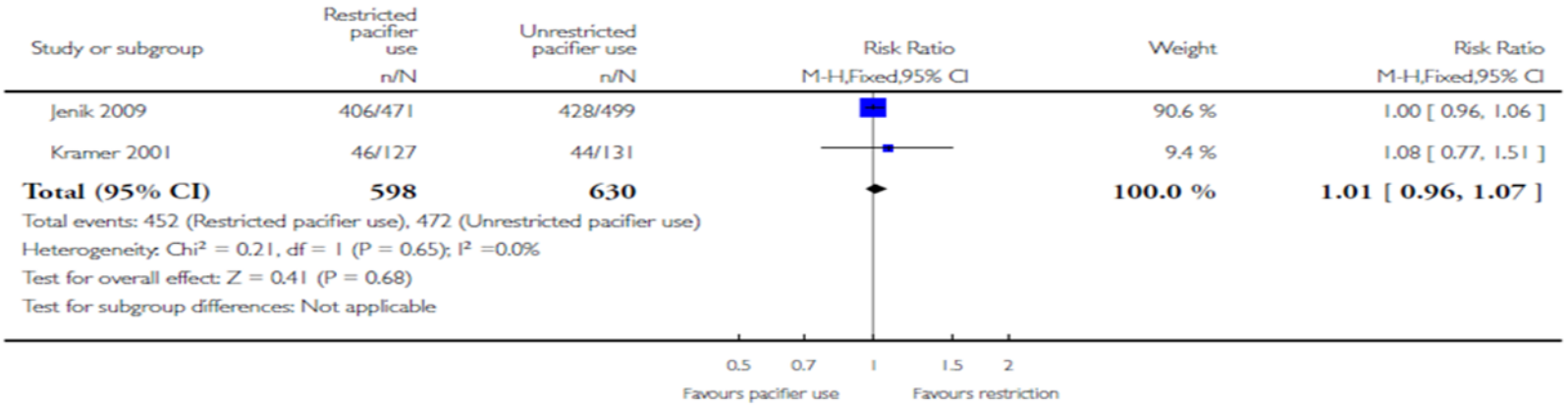
Appraisal 評讀

**Analysis 1.1. Comparison 1 Restricted pacifier use versus unrestricted, Outcome 1 Proportion of infants exclusively breastfed at 3 months.**

Review: Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

Comparison: 1 Restricted pacifier use versus unrestricted

Outcome: 1 Proportion of infants exclusively breastfed at 3 months




## 評讀結果

1.低異質性(Heterogeneity)分析：使用$I^2$ statistic =0

3個月exclusively breastfed 95%CI 0.96 to 1.07, $I^2$ 0%(低度異質性,**合理合併**)

4個月exclusively breastfed 95%CI 0.94 to 1.09, $I^2$ 0%(度異質性,**合理合併**)

3個月partially breastfed 95%CI 0.98 to 1.02, $I^2$ 0%(低度異質性,**合理合併**)

4個月partially breastfed 95%CI 0.97 to 1.02, $I^2$ 0%(度異質性,**合理合併**)

2.使用次族群分析。

3.若超過10篇，會使用Funel plot分析

# 文獻評讀摘要: Validity效度

| | YES | NO |
|---|---|---|
| 1.是否問了一個明確的臨床問題? |  | |
| 2. 是否收納適當的研究類型? |  | |
| 3.有無遺漏重要相關研究? | |  |
| 4.是否評估收納研究品質? |  | |
| 5. 結果是否合併?是否合理? |  | |

# Importance

## 6.此篇結果為何?

# 主要結果---exclusively breastfed at 3 months

Appraisal 評讀

**Analysis 1.1. Comparison 1 Restricted pacifier use versus unrestricted, Outcome 1 Proportion of infants exclusively breastfed at 3 months.**

Review: Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

Comparison: 1 Restricted pacifier use versus unrestricted

Outcome: 1 Proportion of infants exclusively breastfed at 3 months

| Study or subgroup | Restricted pacifier use n/N | Unrestricted pacifier use n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Jenik 2009 | 406/471 | 428/499 | | 90.6 % | 1.00 [ 0.96, 1.06 ] |
| Kramer 2001 | 46/127 | 44/131 | | 9.4 % | 1.08 [ 0.77, 1.51 ] |
| **Total (95% CI)** | **598** | **630** | | **100.0 %** | **1.01 [ 0.96, 1.07 ]** |

Total events: 452 (Restricted pacifier use), 472 (Unrestricted pacifier use)

Heterogeneity: $Chi^2 = 0.21$, $df = 1$ ($P = 0.65$); $I^2 = 0.0\%$

Test for overall effect: $Z = 0.41$ ($P = 0.68$)

Test for subgroup differences: Not applicable


## 評讀結果

| Intervention | Restricted pacifier use |
|---|---|
| **Comparison** | Unrestricted |
| **Time** | 3月 |
| **Results** | 95%CI 0.96 to 1.07, I2 0%(低度異質性,合理合併) |
| **結論** | 是否使用奶嘴不會影響3個月時的完全哺乳比例 ，低異質性，適當呈現結果。 |

# 主要結果---partially breastfed at 3 months

Appraisal 評讀

**Analysis 1.2. Comparison 1 Restricted pacifier use versus unrestricted, Outcome 2 Proportion of infants partially breastfed at 3 months.**

Review: Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

Comparison: 1 Restricted pacifier use versus unrestricted

Outcome: 2 Proportion of infants partially breastfed at 3 months

| Study or subgroup | Restricted pacifier use n/N | Unrestricted pacifier use n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Jenik 2009 | 468/471 | 494/499 | | 82.0 % | 1.00 [ 0.99, 1.02 ] |
| Kramer 2001 | 103/127 | 107/131 | | 18.0 % | 0.99 [ 0.88, 1.12 ] |
| **Total (95% CI)** | **598** | **630** | | **100.0 %** | **1.00 [ 0.98, 1.02 ]** |

Total events: 571 (Restricted pacifier use), 601 (Unrestricted pacifier use)

Heterogeneity: $Chi^2 = 0.13$, df = 1 (P = 0.72); $I^2 = 0.0\%$

Test for overall effect: Z = 0.15 (P = 0.88)

Test for subgroup differences: Not applicable


## 評讀結果

| Intervention | Restricted pacifier use |
|---|---|
| Comparison | Unrestricted |
| Time | 3月 |
| Results | 95%CI 0.98 to 1.02, I2 0%(低度異質性,合理合併) |
| 結論 | 是否使用奶嘴不會影響3個月時的部分哺乳比例 ，低異質性，適當呈現結果。 |

# 主要結果---exclusively breastfed at 4 months

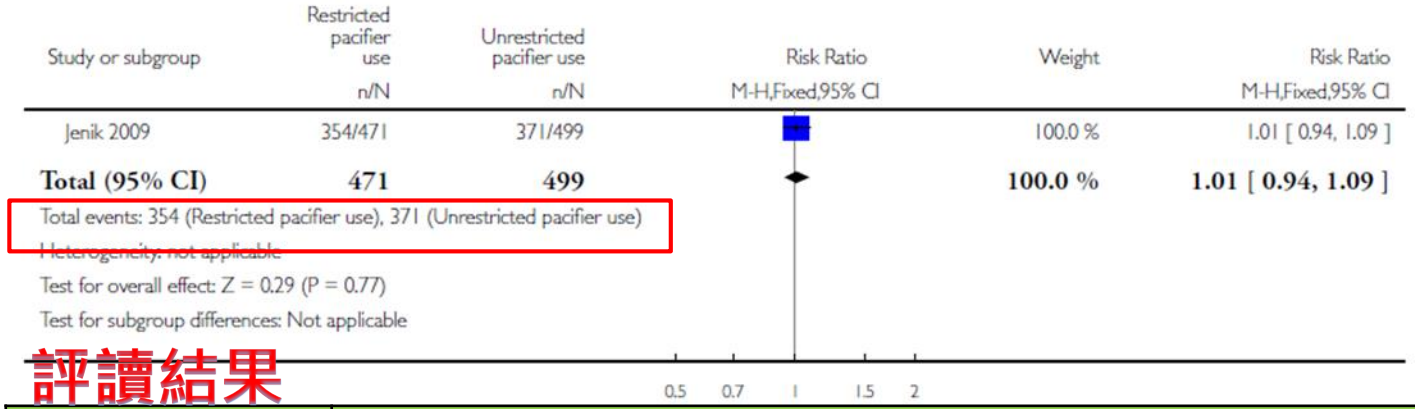
Appraisal 評讀

**Analysis 1.3. Comparison 1 Restricted pacifier use versus unrestricted, Outcome 3 Proportion of infants exclusively breastfed at 4 months.**

Review: Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

Comparison: 1 Restricted pacifier use versus unrestricted

Outcome: 3 Proportion of infants exclusively breastfed at 4 months




## 評讀結果

| Intervention | Restricted pacifier use |
|---|---|
| Comparison | Unrestricted |
| Time | 4月 |
| Results | 95%CI 0.94 to 1.09, I2 0%(度異質性,合理合併) |
| 結論 | 是否使用奶嘴不會影響4個月時的完全哺乳比例 ，低異質性，適當呈現結果。 |

# 主要結果---partially breastfed at 4 months

Appraisal 評讀

**Analysis 1.4. Comparison 1 Restricted pacifier use versus unrestricted, Outcome 4 Proportion infants partially breastfed at 4 months.**

Review: Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

Comparison: 1 Restricted pacifier use versus unrestricted

Outcome: 4 Proportion infants partially breastfed at 4 months

| Study or subgroup | Restricted pacifier use n/N | Unrestricted pacifier use n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Jenik 2009 | 452/471 | 482/499 | | 100.0 % | 0.99 [ 0.97, 1.02 ] |
| **Total (95% CI)** | **471** | **499** | | **100.0 %** | **0.99 [ 0.97, 1.02 ]** |

Total events: 452 (Restricted pacifier use), 482 (Unrestricted pacifier use)

Heterogeneity: not applicable

Test for overall effect: Z = 0.52 (P = 0.61)

Test for subgroup differences: Not applicable


## 評讀結果

| Intervention | Restricted pacifier use |
|---|---|
| Comparison | Unrestricted |
| Time | 4月 |
| Results | 95%CI 0.97 to 1.02, I2 0%(度異質性,合理合併) |
| 結論 | 是否使用奶嘴不會影響4個月時的部分哺乳比例 ，低異質性，適當呈現結果。 |

# 次要結果—

Appraisal
評讀

**Secondary outcomes**

Kramer 2001 reported that avoidance of pacifiers had no effect on cry/fuss behavior at ages four, six, or nine months and had no effect on the risk of weaning before age three months. However, the data were incomplete for analysis. None of the included studies reported data on breastfeeding difficulties (mastitis, cracked nipples, breast engorgement); infant's health (dental malocclusion, otitis media, oral candidiasis, sudden infant death syndrome (SIDS)); and maternal satisfaction and level of confidence in parenting.

# 7.結果精確性如何?

Appraisal
評讀

**Analysis 1.1. Comparison 1 Restricted pacifier use versus unrestricted, Outcome 1 Proportion of infants exclusively breastfed at 3 months.**

Review: Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

Comparison: 1 Restricted pacifier use versus unrestricted

Outcome: 1 Proportion of infants exclusively breastfed at 3 months

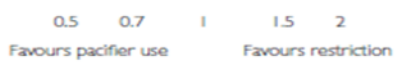
| Study or subgroup | Restricted pacifier use n/N | Unrestricted pacifier use n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Jenik 2009 | 406/471 | 428/499 | | 90.6 % | 1.00 [ 0.96, 1.06 ] |
| Kramer 2001 | 46/127 | 44/131 | | 9.4 % | 1.08 [ 0.77, 1.51 ] |
| **Total (95% CI)** | **598** | **630** | | **100.0 %** | **1.01 [ 0.96, 1.07 ]** |

Total events: 452 (Restricted pacifier use), 472 (Unrestricted pacifier use)

Heterogeneity: $Chi^2 = 0.21$, $df = 1$ ($P = 0.65$); $I^2 = 0.0\%$

Test for overall effect: $Z = 0.41$ ($P = 0.68$)

Test for subgroup differences: Not applicable




**評讀結果**

## 評讀結果精確性

1.納入之寶寶與媽媽有相似的年齡，healthy newborn，。

2.收錄之RCT異質性低，有相似的研究結果。

3.結果之95%信賴區間窄95%CI 0.96, 1.07]。

4.本研究已做次族群分析，且異質性低。

**◉Yes ○No ○Unclear**

# 評定證據等級

**Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence**

| Question | Step 1 (Level 1*) | Step 2 (Level 2*) | Step 3 (Level 3*) | Step 4 (Level 4*) | Step 5 (Level 5) |
|---|---|---|---|---|---|
| **How common is the problem?** | Local and current random sample surveys (or censuses) | Systematic review of surveys that allow matching to local circumstances** | Local non-random sample** | Case-series** | n/a |
| **Is this diagnostic or monitoring test accurate?** (Diagnosis) | Systematic review of cross sectional studies with consistently applied reference standard and blinding | Individual cross sectional studies with consistently applied reference standard and blinding | Non-consecutive studies, or studies without consistently applied reference standards** | Case-control studies, or "poor or non-independent reference standard** | Mechanism-based reasoning |
| **What will happen if we do not add a therapy?** (Prognosis) | Systematic review of inception cohort studies | Inception cohort studies | Cohort study or control arm of randomized trial* | Case-series or case-control studies, or poor quality prognostic cohort study** | n/a |
| **Does this intervention help?** (Treatment Benefits) | Systematic review of randomized trials or *n*-of-1 trials | Randomized trial or observational study with dramatic effect | Non-randomized controlled cohort/follow-up study** | Case-series, case-control studies, or historically controlled studies** | Mechanism-based reasoning |
| **What are the COMMON harms?** (Treatment Harms) | Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect | Individual randomized trial or (exceptionally) observational study with dramatic effect | Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)** | Case-series, case-control, or historically controlled studies** | Mechanism-based reasoning |
| **What are the RARE harms?** (Treatment Harms) | Systematic review of randomized trials or *n*-of-1 trial | Randomized trial or (exceptionally) observational study with dramatic effect | | | |
| **Is this (early detection) test worthwhile?** (Screening) | Systematic review of randomized trials | Randomized trial | Non -randomized controlled cohort/follow-up study** | Case-series, case-control, or historically controlled studies** | Mechanism-based reasoning |

[介入型問題]
RCT系統性文獻回顧
證據等級**Level 1**

# 評定證據等級—GRADE online

●不嚴重　●嚴重　●很嚴重

| | | 主要結果 | 次要結果 |
|---|---|---|---|
| 研究設計 | | RCT | RCT |
| 降階 | 1.存在誤差風險 | ● | ● |
| | 2.結果不一致 | ● | ● |
| | 3.證據不具直接性 | ● | ● |
| | 4.結果不精準 | ● | ● |
| | 5.存在發表誤差 | ● | ● |
| 升階 | 1.效果顯著 | - | - |
| | 2.降低干擾因素 | - | - |
| | 3.具劑量-反應效果 | - | - |
| **證據等級** | | ⊕⊕⊕⊕ HIGH | ⊕⊕⊕⊕ HIGH |

Practice

# 8.是否所有重要臨床結果都被考量到?

# 8.是否所有重要臨床結果都被考量到? Yes ☑ No □ Unclear □

Appraisal 評讀

We included two out of three RCTs enrolling 1302 healthy full-term breastfeeding infants for meta-analysis (Jenik 2009; Kramer 2001). Both of the trials contributed to at least one of the primary outcomes, i.e. proportion of infants partially or exclusively breastfed at three and four months of age. Comparison between restricted pacifier use (intervention) and unrestricted pacifier use (control) revealed that there was no difference in the proportion of infants exclusively breastfed at three months (risk ratio (RR) 1.01; 95% confidence interval (CI) 0.96 to 1.07, two studies, 1228 babies, $I^2$ = 0%, (Analysis 1.1)) and at four months of age (RR 1.01; 95% CI 0.94 to 1.09, one study, 970 babies, *moderate-quality evidence* (Analysis 1.3)). There was also no difference in the proportion of infants partially breastfed at three months (RR 1.00; 95%; CI 0.98 to 1.02, two studies, 1228 babies, $I^2$ = 0%, (Analysis 1.2)), or at four months (RR 0.99; 95% CI 0.97 to 1.02, one study, 970 babies (Analysis 1.4)). Thus, restricted or no pacifier use in full-term breastfeeding infants after birth or after the establishment of lactation did not significantly affect the prevalence or duration of exclusive or partial breastfeeding up to the age of four months. None of the included studies reported data on the other primary outcomes, i.e. duration of partial or exclusive breastfeeding.

**Secondary outcomes**

Kramer 2001 reported that avoidance of pacifiers had no effect on cry/fuss behavior at ages four, six, or nine months and had no effect on the risk of weaning before age three months. However, the data were incomplete for analysis. None of the included studies reported data on breastfeeding difficulties (mastitis, cracked nipples, breast engorgement); infant's health (dental malocclusion, otitis media, oral candidiasis, sudden infant death syndrome (SIDS));

**評讀結果**

1.除了上面所探討的主要結果外，作者而外還整理的四個 secondary outcome

2.除了優點外，吃奶嘴的缺點也有做相關搜尋。

# Practice

## 9.好處所帶來的傷害和花費?是否值得?

# Cost effect

*Health Technology Assessment* 2009; Vol. 13: No. 40

## Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis

MJ Renfrew, D Craig, L Dyson,
F McCormick, S Rice, SE King,
K Misso, E Stenhouse and AF Williams

per infant and ranged from £66 to £586 cheaper per infant across the birthweight subpopulations. Donor milk would become cost-effective given improved mechanisms for its provision.

**Conclusions:** Despite the limitations of the evidence base, kangaroo skin-to-skin contact, peer support, simultaneous breastmilk pumping, multidisciplinary staff training and the Baby Friendly accreditation of the associated maternity hospital have been shown to be effective, and skilled support from trained staff in hospital has been shown to be potentially cost-effective. All these point to future research priorities. Many of these interventions inter-relate: it is unlikely that specific clinical interventions will be effective if used alone. There is a need for national surveillance of feeding, health and cost outcomes for infants and mothers in neonatal units; to assist this goal, we propose consensus definitions of the initiation and duration of breastfeeding/breastmilk feeding with specific reference to infants admitted to neonatal units and their mothers.

# 效益分析—病患從此介入獲得的好處

Appraisal
評讀

| 主要結果: | | |
|---|---|---|
| 研究(人數) | Odds ratio | NNT |
| 2項<br>(1228人) | 0.949 | 20000 |

此文章提供了臨床問題的重要結果，可推算**NNT**

主要結果:有無限制新生兒使嘴，並不會引響其於3-4個月吸母奶情形

主要副作用:新生兒健康、奶嘴戒斷、新生兒猝死及媽媽乳腺炎並無文獻提及 ✓**Yes** ○**No** ○**Unclear**

# 成本效益—

Appraisal
評讀

| 藥物 | 優點 | 缺點(副作用) | 市售單價 |
| --- | --- | --- | --- |
| 奶嘴 | | | 150元/顆 |
| 配方奶 | | | 800元/瓶<br>2500元/月 |
| 其他家庭社會成本 | | | 無法確切評估 |

Practice

# 10.是否可應用到在我們的病人身上?

# 評估適用性—比較評讀文獻及臨床情境

Appraisal
評讀

| | 臨床情境 | 評讀文獻 |
|---|---|---|
| P | 新生兒 | 健康的足月產新生兒 |
| I | 限制奶嘴使用 | 限制奶嘴使用 |
| C | 沒有限制奶嘴使用 | 沒有限制奶嘴使用 |
| O | 益處：被哺育母乳的時間<br>可能的害處:影響新生兒健康、新生兒死亡 | 新生兒在3,4個月時被完全或部分哺乳的比例<br>新生兒健康、新生兒猝死 |

# 臨床應用

| | |
|---|---|
| 我們的病患與研究是否相似? | Yes　No　Unclear |
| 此治療方式在本地可實行嗎? | Yes　No　Unclear |
| 使否符合病人的訴求? | Yes　No　Unclear |

Yes　○No　○Unclear

Appraisal
評讀

| 評讀結果 | Yes | No | Unclear |
| --- | --- | --- | --- |
| 1.臨床問題是否明確? | ✓ | | |
| 2.是否收納適當研究類型? | ✓ | | |
| 3.有無遺漏重要相關研究? | ✓ | | |
| 4.是否評估收納研究品質? | ✓ | | |
| 5.結果是否合併?是否合理? | ✓ | | |
| 6.此篇結果為何? | ✓ | | |
| 7.結果精確性如何? | ✓ | | |
| 8.是否可應用到在我們的病人身上? | ✓ | | |
| 9.是否所有重要臨床結果都被考量到? | ✓ | | |
| 10.好處所帶來的傷害和花費?是否值得? | ✓ | | |

# 決策共享-Share Decision Making

| 1.實證證據Evidence | 2.病人的偏好與期望Expectation |
| --- | --- |
| 目前最佳證據顯示(GRADE高強度建議)，有無限制奶嘴的使用，並不會影響新生兒的母乳哺餵時間。 | 病人看寶寶一直哭很心疼，希望給寶寶吃一下安撫奶嘴。 |
| **3.利弊平衡** | **4.現實考量Environment** |
| **好處:**使用安撫奶嘴可能可以安撫寶寶並不會影響新生兒的母乳哺餵時間。<br><br>**壞處:**目前無文獻證據顯示有明顯壞處。 | 使用安撫奶嘴可能可以安撫寶寶並不會影響新生兒的母乳哺餵時間，若未選擇哺餵母乳選擇配方奶，則費用約2500元/月。其他影響哺餵母乳因素過多，費用資源無法確切評估。 |

# 回覆病人的問題

爸爸媽媽您好，透過我們的實證搜尋後，目前最佳證據顯示，有無限制奶嘴的使用，並不會影響新生兒的母乳哺餵時間。，也無文獻證據顯示有明顯壞處。若寶寶有哭鬧情形，能試著使用安撫奶嘴，安撫寶寶。

.感謝各位評審聆聽.

THANK YOU SO MUCH FOR YOUR ATTENTION

T.S.G.H.

以病人為中心的實證醫療照護