Systematic Review Protocol

The effectiveness of lactation consultants on breastfeeding outcomes

**Primary reviewer**
Sanjay Patel  
11635 Northpark Drive  
Wake Forest, NC 27587  
Phone: 919-570-6060  
Email: sanjay.patel@duke.edu

**Secondary reviewer**
Shveta Patel RN, BSN, IBCLC  
Public Health Nurse  
Care Coordination for Children  
Northern Region Center  
350 East Holding Avenue  
Wake Forest, NC 27587  
Phone: 919-562-6318  
Email: shveta.patel@wakegov.com

**Contact person**
Sanjay Patel  
11635 Northpark Drive  
Wake Forest, NC 27587  
Phone: 919-570-6060  
Email: sanjay.patel@duke.edu

**Commencement date:** October 1, 2013

**Expected completion date:** September 30, 2014
Background
Breastfeeding for all infants starting at birth and continuing till up to at least six months of age has been recommended by various agencies including the World Health Organization (WHO) and the American Academy of Pediatrics. The health benefits to infants and mothers have been demonstrated in many studies. (1) For this reason, the United States Preventive Service Task Force (USPTF) recommends policies that promote and support breastfeeding both during pregnancy and after birth. In the US, various strategies have been implemented to increase breastfeeding initiation and duration. Studies have shown that breastfeeding support interventions increase breastfeeding initiation and duration. (2) With any breastfeeding intervention one must look at 3 key questions. What is the timing of the intervention? Who will promote, provide, and support the breastfeeding intervention? How and where will the intervention be delivered?

Professional breastfeeding support includes any counseling or behavioral interventions to improve breastfeeding outcomes. The primary focus of support is counseling, encouragement, and management of lactation crises. The support can be implemented during pregnancy, intrapartum, or postpartum. It can be rendered in person or over the telephone, in a clinic, or in a home setting. It can be given one-on-one or in a group setting. (3)

Dedicated certified lactation specialists, lactation consultants, and counselors may play an important role in providing this support to ensure high initiation and maintenance rates for breastfeeding. Health care professionals and non-professionals can be trained as lactation consultants, and are certified through the International Board of Lactation Consultant Examiners (IBLCE). Community centers and hospitals can employ consultants for inpatient as well as outpatient settings. The consultants can work independently. Their role is to provide care and support to nursing families in meeting their breastfeeding goals, in addition to working hand-in-hand with prenatal and postpartum providers to help establish and support protocols for exclusive breastfeeding. An International Board Certified Lactation Consultant (IBCLC) obtains certification through the IBLCE by demonstrating clinical competence and satisfying the certification exam. Recertification is every five years through the completion of required continuing education. The recertification exam is every ten years. (4)

Certified lactation counselors (CLC) receive training and competency certification in breastfeeding and human lactation support through various agencies. The training involves forty-five hours of didactic and experiential activities during a five day course along with satisfying an assessment test. Recertification is every three years by completing eighteen hours of required continuing education in breastfeeding and human lactation. Much like the IBCLC,
the CLC, works in a variety of healthcare settings to provide counseling and support to breastfeeding infants, children and their mothers. (5)

Systematic reviews in the past have looked at the impact of breastfeeding support in general. Presently, there are many breastfeeding interventions being used in the US depending on the setting, the resources available, and the population being served. Some interventions are more effective than others. This review will look at the impact of lactation consultants and counselors on breastfeeding outcomes. This information will help policy makers in health systems make decisions on whether to incorporate these professionals in their breastfeeding support programs.

**Objectives**
The objective of this review is to assess if a lactation support program utilizing lactation consultants or lactation counselors, will improve rates of initiation and duration of breastfeeding and exclusive breastfeeding compared with usual practice. Secondary objectives will assess whether the intervention would improve maternal and healthcare staff satisfaction or improve maternal or infant outcomes.

**Methods**
**Search strategy:**
The primary reviewer will use the following strategy to identify potentially relevant citations for this review.

- MESH and keyword search terms: Lactation consultant, Lactation counselors, breastfeeding support, breastfeeding, lactation, outcomes, initiation rates, duration, exclusive breastfeeding
- Electronic biomedical databases and or resources: Cochrane Library, EMBASE, CINAHAL, Medline, DARE, Google Scholar, Global Health, ClinicalTrials.gov, hand search of references
- Language restrictions: Studies published in the English language
- Type of Study: Controlled trials, Randomized control trials (RCTs), Non-randomized controlled trials (NRCTs), Quasi-experimental studies, Controlled before-after studies (CBAs), Interrupted time series studies (ITSs)
- Time Period: studies from year 1985 till January 2014

**Inclusion criteria:**
All relevant citations will be imported into an Endnote database for reference. Full text of the studies will be obtained. The primary and secondary reviewers will then review the full text
reports to assess the studies against the inclusion criteria. Discrepancies will be resolved by discussion. The following criteria will be used to include studies in this review.

Types of Studies

The IBLCE was established in 1985. The review will include any relevant published studies undertaken between January 1985 and January 2014.

- Controlled clinical trials
- Randomized controlled trials
- Non-randomized controlled trials
- Quasi-experimental studies
- Controlled before-after studies
- Interrupted time series studies (studies with at least three data points before and after implementation of the intervention which have a clearly defined point in time when the intervention occurred)
- Case studies will be excluded
- English language studies conducted in the developed countries in Asia, Europe, North America, Australia, and New Zealand

The number of high quality randomized control trials pertaining to this review may be limited. Because of the inherent difficulty in performing randomized control trials involving the use of lactation consultants within complex organizational interventions or public policy campaigns, non-randomized controlled studies will be included in the review. It is important to recognize that these studies may be affected by bias from confounding factors, and that there may be significant heterogeneity. However, the studies may give some insight into the design of future randomized trials involving lactation consultants. The evidence from non-randomized controlled trials will be presented separately from evidence that is documented from randomized control trials.

Population/Participants

- Newborns (including preemies and term infants) and their mothers, pregnant women, or women who may in the future decide to breastfeed, healthcare staff providing support
- The population/participants will have been exposed to interventions as part of programs looking at outcomes pertaining to breastfeeding

Intervention

- International Board Certified Lactation Consultant (IBCLC)
- Certified Lactation Counselor (CLC)
- Lactation consultant
- Lactation counselor

Studies combining lactation consultants and counselors, as well as other professional or breastfeeding support, will be included in the study. Studies relevant would be those
looking at the use of International Board Certified Lactation Consultants, Certified Lactation Counselor, lactation consultants or lactation counselors in breastfeeding programs for interventions that could include counseling, structured education or support for the maternal/infant unit, as well as the healthcare team or system providing the breastfeeding support (staff training). Interventions may be stand alone or be part of a multi-component structured program.

Comparator
- Usual care defined within each study for women in the control groups

Outcomes
- Primary outcomes
  1. Breastfeeding initiation rates
  2. Breastfeeding duration
  3. Exclusive breastfeeding rates at 1 month, 3 months and 6 months

The World Health Organization defines exclusive breastfeeding as infants receiving *only* breast milk from his or her mother, or a wet nurse, or expressed breast milk, *and* no other liquids or solids other than vitamins, minerals or medications. (6) The definitions of breastfeeding categories will vary from study to study and may not conform to the World Health Organization’s definitions.

- Secondary outcomes
  1. Maternal satisfaction
  2. Staff/Healthcare team satisfaction
  3. Maternal or infant health outcomes

Study Eligibility, Data Collection and Characteristics of Included Studies Forms
- Appendix A
- Appendix B

**Data collection/abstraction:**
The primary and secondary reviewer will independently abstract and collect data pertaining to the review using the data extraction form (Appendix A), which was modified from the Joanna Briggs Institute (JBI) Data Extraction Form for Experimental and Observational Studies. (7) The data abstracted will include the following:

- **Methods**
  - Study design
  - Total study duration
- **Participants**
  - Population characteristics (country, setting, co-morbidity, socio-demographics, race/ethnicity)
- **Interventions**
Total number of intervention groups

Intervention details

- **Outcomes**
  Outcome description and measure: Primary outcomes include breastfeeding initiation rates, breastfeeding duration, or exclusive breastfeeding rates. Secondary outcomes include maternal satisfaction, staff/healthcare team satisfaction, or maternal/infant health outcomes. Any additional information relating to duration and/or exclusivity of breastfeeding will also be reported.

- **Results**
  Summary data for each intervention group
  Missing participants and handling of missing participants
  Summary of narrative results

- **Miscellaneous**
  Key conclusions of the study authors
  Miscellaneous comments from the study authors
  References to other relevant studies
  Funding source
  Correspondence required
  Miscellaneous comments from the study authors

**Critical appraisal:**
The primary and secondary reviewer will independently assess the studies for methodological quality. Discrepancies will be resolved by discussion.

- Risk of bias assessment will be done using the suggested risk of bias criteria developed by the Cochrane Effective Practice and Organization of Care (EPOC) Group. (8)
- Nine standard criteria will be used to assess Randomized control trials (RCTs), Non-randomized controlled trials (NRCTs), and Controlled before-after studies (CBAs).
  - Was the allocation sequence adequately generated?
  - Was the allocation adequately concealed?
  - Were baseline outcome measurements similar?
  - Were incomplete data adequately addressed?
  - Was knowledge of the intervention(s) adequately prevented during the study?
  - Was the study adequately protected against contamination?
  - Was the study free from selective outcome reporting?
  - Was the study free from other risk of bias?
- Seven standard criteria will be used to assess Interrupted time series studies (ITSs).
  - Was the intervention independent of other changes?
  - Was the shape of the intervention effect pre-specified?
Was the intervention unlikely to affect data collection?
Was knowledge of the allocated interventions adequately prevented during the study?
Were incomplete outcome data adequately addressed?
Was the study free from selective outcome reporting?
Was the study free from other risks of bias?

Study Quality Forms for studies included in the review have been developed using the suggested criteria.
- Appendix C

Data synthesis:
All data will be double entered. For studies reporting dichotomous data relative risk/risk ratio (RR) or odds ratio (OR) with corresponding 95% confidence intervals will be calculated. For continuous data, mean differences with 95% confidence intervals will be calculated. Forest plots will be used to summarize the findings from trials included in the review. Randomized trials will be assessed for clinical and methodological heterogeneity, as well as statistical heterogeneity. A meta-analysis, if appropriate, using Review Manager (Rev Man 5) may be performed. The studies may be too diverse or it may be inappropriate statistically to pool the results from the studies. In this case, the findings will be summarized in narrative form.
References


8. Effective Practice and Organization of Care (EPOC). EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services; 2013. Available at: http://epocoslo.cochrane.org/epoc-specific-resources-review-authors
Appendix A:

Title of review: The effectiveness of lactation consultants on breastfeeding outcomes

Study Eligibility, Data Collection

Version of Review: 1

Reviewer Date

Study Title/ID

Author/s

Date of study Publication date

Total study duration

Inclusion Criteria

1. Does the study meet the inclusion criteria for the type of study?
   Yes No Unclear

   Type of Study
   Controlled clinical trial Randomized control trial (RCT) Non randomized trial
   Quasi-experimental study Controlled before-after studies (CBA)
   Interrupted time series (ITS)
   Other

2. Does the study meet the inclusion criteria for the population/participants being evaluated?
   Yes No Unclear
<table>
<thead>
<tr>
<th>Population/Participant type</th>
<th>High risk pregnant women</th>
<th>Pregnant women</th>
<th>Preemie/mom</th>
<th>Term/mom</th>
<th>Healthcare staff</th>
<th>Other</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Healthcare staff</th>
<th>Other</th>
</tr>
</thead>
</table>

3. Does the study meet the inclusion criteria for the intervention being evaluated?

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBCLC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactation consultants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactation counselors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Does the study meet the inclusion criteria for defining the comparator?

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Does the study meet the inclusion criteria for clearly defining and reporting outcomes?

<table>
<thead>
<tr>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breastfeeding initiation rates</td>
</tr>
<tr>
<td>Any breastfeeding rates</td>
</tr>
<tr>
<td>Exclusive breastfeeding rates</td>
</tr>
<tr>
<td>Breastfeeding intensity</td>
</tr>
</tbody>
</table>
Breastfeeding duration and maintenance rates

Maternal satisfaction

Staff/Healthcare team satisfaction

Maternal or infant health outcomes

Other

If all criteria met include.

**Final decision**
Include and proceed to below to Data Collection  Exclude

If excluded why?

Data Collection

**Participants**
Total number of participants in study

Country  Setting

Co-morbidity (high risk, preemie, etc)

Socio-demographics

Ethnicity/Race

Interventions
Total number of intervention groups
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Intervention details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome Description</td>
</tr>
<tr>
<td>Outcome Description</td>
</tr>
<tr>
<td>Outcome Description</td>
</tr>
<tr>
<td>Outcome Description</td>
</tr>
<tr>
<td>Outcome Description</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dichotomous Data</td>
</tr>
<tr>
<td>Intervention Outcome</td>
</tr>
<tr>
<td>Intervention Outcome</td>
</tr>
<tr>
<td>Intervention Outcome</td>
</tr>
<tr>
<td>Intervention Outcome</td>
</tr>
<tr>
<td>Intervention Outcome</td>
</tr>
</tbody>
</table>
### Continuous data

<table>
<thead>
<tr>
<th>Intervention Outcome</th>
<th>Mean difference, Standardized mean difference, other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of missing participants and handling of missing participants in each intervention group

Summary of narrative results
**Miscellaneous**
Key conclusions of the study authors

Miscellaneous comments from the study authors

References to other relevant studies

Funding source

Correspondence required?

Miscellaneous comments by the review authors
Appendix B:

Title of review: The effectiveness of lactation consultants on breastfeeding outcomes

Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix C:
Study Quality Form

Title of review: The effectiveness of lactation consultants on breastfeeding outcomes

Version of Review: 1

Reviewer
Date

Study Title/Citation

Risk of bias for studies with a separate control group
Randomized controlled trials (RCTs)
Non-randomized controlled trials (NRCTs)
Controlled before-after (CBA) studies

1. Was the allocation sequence adequately generated?
Score “Low risk” if a random component in the sequence generation process is described (e.g. Referring to a random number table). Score “High risk” when a nonrandom method is used (e.g. performed by date of admission). NRCTs and CBA studies should be scored “High risk”. Score “Unclear risk” if not specified in the paper.
(Low, Unclear, High)

2. Was the allocation adequately concealed?
Score “Low risk” if the unit of allocation was by institution, team or professional and allocation was performed on all units at the start of the study; or if the unit of allocation was by patient or episode of care and there was some form of centralized randomization scheme, an on-site computer system or sealed opaque envelopes were used. CBA studies should be scored “High risk”. Score “Unclear risk” if not specified in the paper.
(Low, Unclear, High)

3. Were baseline outcome measurements similar?
Score “Low risk” if performance or patient outcomes were measured prior to the intervention, and no important differences were present across study groups. In RCTs, score “Low risk” if imbalanced but appropriate adjusted analysis was performed (e.g. Analysis of covariance). Score “High risk” if important differences were present and not adjusted for in analysis. If RCTs have no baseline measure of outcome, score “Unclear risk”.


4. Were baseline characteristics similar?
Score “Low risk” if baseline characteristics of the study and control providers are reported and similar. Score “Unclear risk” if it is not clear in the paper (e.g. characteristics are mentioned in text but no data were presented). Score “High risk” if there is no report of characteristics in text or tables or if there are differences between control and intervention providers. Note that in some cases, imbalance in patient characteristics may be due to recruitment bias whereby the provider was responsible for recruiting patients into the trial.

5. Were incomplete data adequately addressed?
Score “Low risk” if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the intervention and control groups or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). Score “High risk” if missing outcome data was likely to bias the results. Score “Unclear risk” if not specified in the paper (Do not assume 100% follow up unless stated explicitly).

6. Was knowledge of the intervention(s) adequately prevented during the study?
Score “Low risk” if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective, e.g. length of hospital stay. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. Score “High risk” if the outcomes were not assessed blindly. Score “Unclear risk” if not specified in the paper.

7. Was the study adequately protected against contamination?
Score “Low risk” if allocation was by community, institution or practice and it is unlikely that the control group received the intervention. Score “High risk” if it is likely that the control group received the intervention (e.g. if patients rather than professionals were randomized). Score “Unclear risk” if professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control).

8. Was the study free from selective outcome reporting?
Score “Low risk” if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). Score “High risk”
if some important outcomes are subsequently omitted from the results. Score “Unclear risk” if not specified in the paper.
(Low, Unclear, High)

9. Was the study free from other risk of bias?
Score “Low risk” if there is no evidence of other risk of biases.
(Low, Unclear, High)

Risk of bias for interrupted time series (ITS) studies

1. Was the intervention independent of other changes?
Score “Low risk” if there are compelling arguments that the intervention occurred independently of other changes over time and the outcome was not influenced by other confounding variables/historic events during study period. If Events/variables identified, note what they are. Score “High risk” if reported that intervention was not independent of other changes in time.
(Low, Unclear, High)

2. Was the shape of the intervention effect pre-specified?
Score “Low risk” if point of analysis is the point of intervention or a rational explanation for the shape of intervention effect was given by the author(s). Where appropriate, this should include an explanation if the point of analysis is not the point of intervention. Score “High risk” if it is clear that the condition above is not met.
(Low, Unclear, High)

3. Was the intervention unlikely to affect data collection?
Score “Low risk” if reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention). Score “High risk” if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported).
(Low, Unclear, High)

4. Was knowledge of the allocated interventions adequately prevented during the study?
Score “Low risk” if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective, e.g. length of hospital stay. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the
authors. Score “High risk” if the outcomes were not assessed blindly. Score “Unclear risk” if not specified in the paper.
(Low, Unclear, High)

5. Were incomplete outcome data adequately addressed?
Score “Low risk” if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the pre- and post-intervention periods or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). Score “High risk” if missing outcome data was likely to bias the results. Score “Unclear risk” if not specified in the paper (Do not assume 100% follow up unless stated explicitly).
(Low, Unclear, High)

6. Was the study free from selective outcome reporting?
Score “Low risk” if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). Score “High risk” if some important outcomes are subsequently omitted from the results. Score “Unclear risk” if not specified in the paper.
(Low, Unclear, High)

7. Was the study free from other risks of bias?
Score “Low risk” if there is no evidence of other risk of biases. Consider if seasonality is an issue (i.e. if January to June comprises the pre-intervention period and July to December the post, could the “seasons’ have caused a spurious effect).
(Low, Unclear, High)