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Support for breastfeeding mothers
Cochrane review update
Protocol

Background

There is extensive evidence of short-term and long-term health benefits of breastfeeding for infants and mothers. Early benefits include reduced mortality in preterm infants (Lucas 1990a), reduced infant morbidity from gastro-intestinal, respiratory, urinary tract and middle-ear infections and less atopic illness (Aniansson 1994; Cesar 1999; Howie 1990; Kramer 2001; Lucas 1990b; Marild 2004). There is some evidence that exclusive breastfeeding is associated with the lowest rates of these illnesses in the first six months of life (Kramer 2002; Raisler 1999).

Breastfeeding offers some protection against the development of childhood diseases such as juvenile onset insulin dependant diabetes mellitus (Sadauskaite 2004; Virtanen 1991); raised blood pressure (Taittonen 1996; Wilson 1998; Singhal 2001); obesity (Fewtrell 2004; Gillman 2001) and the development of diseases in later life such as atopic disease (Fewtrell 2004) and raised blood pressure (Fewtrell 2004; Martin 2004). Breastfeeding has also been associated with significantly higher scores for cognitive development (Anderson 1999; Fewtrell 2004).

As well as health benefits to infants, breastfeeding has an impact on maternal health too (Labbock 2001). Studies have demonstrated a lower incidence of breast cancer (Beral 2002; Newcombe 1994), ovarian cancer (Gwinn 1990; Rosenblatt 1993) and hip fractures (Cumming 1993) in those women who have breastfed.

The established health benefits of breastfeeding to a nation have resulted in global and national support for encouraging the commencement and continuation of breastfeeding. In 2003 the World Health Organization recommended that, wherever possible, infants should be fed exclusively on breast milk until six months of age (WHO 2003). In England two aims are to raise the breastfeeding initiation rate by two percentage points per year (DoH 2002) and to support the World Health Organization recommendation (WHO 2003) of exclusive breastfeeding for the first six months of life (DoH 2003).

Despite the established benefits of breastfeeding, breastfeeding rates in many developed countries continue to be resistant to change. In the UK, the breastfeeding initiation rate was 69% in 2000 (Hamlyn 2002). A similar figure is reported in the US (USDoHHS 2005). However, in both the UK and USA there is a marked decline in breastfeeding within the first few weeks after initiation, and exclusive breastfeeding is rare. Conversely, some other European countries, such as Scandinavia and Germany (Cattaneo 2003), have high initiation and continuation breastfeeding rates (Nicoll 2002).

There are many factors that might influence the early cessation of breastfeeding. In developed countries, young mothers and those in low-income groups or those who ceased full-time

education at an early age are least likely to either start breastfeeding or continue for a period of time sufficient to confer health gain (Hamlyn 2002). Enkin notes that industrial societies, on the whole, do not provide women with the opportunity to observe other breastfeeding women before they attempt breastfeeding themselves (Enkin 2000). In such societies, women are at risk of lack of support to breastfeed their babies. Paradoxically, in poorer countries, more affluent groups may have lower breastfeeding rates (Chhabra 1998; Rogers 1997). This is particularly important as there is a protective effect when breastfeeding continues for long periods of time, resulting in reduced infant mortality and child mortality in the second year of life in less developed countries (WHO 2000).

Although some women will choose to breastfeed their infant for a limited amount of time, or not at all, there is evidence that many women are disappointed that they have not been successful in breastfeeding for longer. Hamlyn 2002 reports that 87% of mothers who ceased breastfeeding within six weeks of birth would have liked to breastfeed for longer. For those mothers who breastfed for at least six months, 37% would have preferred to continue for longer.

Clearly there is a need to review the support mothers receive when breastfeeding to determine what might be effective in helping women continue to breastfeed. The purpose of this review was to examine interventions which provide extra support for mothers who wish to breastfeed; and to assess their impact on breastfeeding duration and exclusivity and, where recorded, on health outcomes and maternal satisfaction. Specific objectives of the review were to describe forms of support which have been evaluated in controlled studies, and the settings in which they have been used. It was also of interest to examine the effectiveness of different modes of offering similar supportive interventions (for example, face-to-face or over the telephone), and whether interventions containing both antenatal and postnatal elements were more effective than those taking place in the postnatal period alone. We also planned to examine the effectiveness of different care providers and training programmes and the effect of baseline breastfeeding prevalence (where known) on the effectiveness of supportive interventions.

Objectives

(1) To describe forms of breastfeeding support which have been evaluated in controlled studies, the timing of the interventions and the settings in which they have been used.

(2) To examine the effectiveness of comparable interventions and compare effectiveness in low- and high-income groups where possible.

(3) To examine the effectiveness of different modes of offering similar supportive interventions (for example, face-to-face or over the telephone), and whether interventions containing both antenatal and postnatal elements were more effective than those taking place in the postnatal period alone.

(4) To compare the effectiveness of different care providers and training.

(5) To explore the interaction between baseline breastfeeding prevalence (where known) and effectiveness of support.

Methods

Criteria for considering studies for this review

Types of studies

All randomised or quasi-randomised controlled trials, with or without blinding, and with a minimum of 75% follow up.

Types of participants

Participants are pregnant women intending to breastfeed, postpartum women intending to breastfeed and women breastfeeding their babies.

Types of interventions

Contact with an individual or individuals (either professional or volunteer) offering support which is supplementary to standard care (in the form of, for example, appropriate guidance and encouragement) with the purpose of facilitating continued breastfeeding. Studies were included if the intervention occurred in the postnatal period alone or also included an antenatal component. Interventions taking place in the antenatal period alone were excluded from this review, as were interventions described as solely educational in nature.

Types of outcome measures

Primary outcomes

1. Cessation of breastfeeding before six months postpartum.
2. Cessation of exclusive breast feeding before six months postpartum.
3. Duration of breastfeeding (continuous outcome).

Secondary outcomes

1. Cessation of breast feeding before six weeks, and three, nine and 12 months postpartum.
2. Cessation of exclusive breastfeeding at three months postpartum.
3. Maternal satisfaction with care.
4. Maternal satisfaction with feeding method.
5. All cause infant or neonatal morbidity.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (31 August 2010).

The Cochrane Pregnancy and Childbirth Group’s Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords.

In previous versions of the review we carried out additional searches of MEDLINE (1966 to November 2005), EMBASE (1974 to November 2005) and handsearched Midwives Information and Resource Service (MIDIRS) quarterly Digest from 1991 to September 2005. We scanned secondary references and obtained relevant studies. Details of the search strategies can be obtained from the review authors. In this updated version of the review we did not carry out these additional searches.

We did not apply any language restrictions.

Data collection and analysis

For the methods used when assessing the trials identified in the previous versions of this review, *see* Appendix 1.

For this update, we used the following methods when assessing the trials identified by the updated search (Agrasada 2005a; Ahmed 2008a; Aidam 2005a; Anderson 2005a; Anderson 2007; Baqui 2008a; Barlow 2006a; Bashour 2008a; Bhandari 2007; Bonuck 2005a; Bonuck 2006; Bonuck 2008a; Brown 2008a, Bunik 2007; Bunik 2007a; Bunik 2007c; Caldeira 2008a; Caulfield 1998a; Coutinho 2005a; de Oliveira 2006a; Ebbeling 2007a; Ekstrom 2006a; Ekstrom 2006a; Eneroth 2007a; Ferrara 2008a; Finch 2002a; Forster 2004; Garcia-Montrone 1996a; Gijsbers 2006a; Gijsbers 2006a; Gijsbers 2008; Hall 2007a; Hoddinott 2006; Hoddinott 2009a; Inch 2003; Isselmann 2006a; Jakobsen 2008a; Jang 2008a; Johnston 2001a; Jones 2004a; Junior 2007a; Kramer 2007; Kramer 2007a; Kramer 2008; Kramer 2008a; Kramer 2009; Kronborg 2007a; Kronborg 2008; Labarere 2005a; Leite 2005; Lewin 2005a; MacArthur 2009a; Mannan 2008a; Memmott 2006; Merewood 2005; Merewood 2006a; Moore 2007; Moreno-Manzanares 1997a; Muirhead 2006a; Noel-Weiss 2006a; Peterson 2002a; Petrova 2009a; Philipp 2004; Pugh 1998a; Pugh 2007a; Ransjo-Arvidson 1998a; Rossiter 1994a; Sakha 2008a; Sinclair 2007a; Sisk 2006a; Stevens 2006; Su 2007a;

Susin 2008a; Thussanasupap 2006a; Tylleskar 2008; Wallace 2006a; Wambach 2006; Wambach 2009a; Zukowsky 2007).

Selection of studies

Two review authors (FM and TD) independently assessed for all the studies identified as a result of the search strategy for possible inclusion in the review. We resolved any disagreement through discussion or, if required, we will consulted a third review author (MJR).

Data extraction and management

We designed and piloted a form to extract data. For eligible studies, two review authors extracted data using the agreed form. We resolved discrepancies through discussion. Data were entered into Review Manager software (RevMan 2008) and checked for accuracy.

When information regarding study methods and results were unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

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 2008). Any disagreement will be resolved by discussion or by involving a third assessor.

(1) Sequence generation (checking for possible selection bias)

We have described for each included study the method used to generate the allocation sequence and assessed whether it was likely to produce comparable groups.

We assessed the method as:

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

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

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

We assessed the methods as:

- adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);

- inadequate (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear.

(3) Blinding (checking for possible performance bias)

For this type of intervention blinding women and clinical staff is generally not feasible, although it may be possible to blind outcome assessors. We have assessed blinding for outcome assessors as:

- adequate, inadequate or unclear.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

In studies examining breast feeding support women may be followed up over many months and loss to follow-up over time may mean that studies are at high risk of bias. We have described for each included study the completeness of data including attrition and exclusions from the analysis. We have reported 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. We assessed methods as:

- adequate;
- inadequate:
- unclear.

We have not included data in the analyses if there was more than 25% missing data.

(5) Selective reporting bias

We described for each included study whether we suspected any selective outcome reporting bias.

We assessed the methods as:

- adequate (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- inadequate (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear.

For outcomes where 10 or more trials contributed data we generated funnel plots and visually examined them for signs of possible publication bias.

(6) Other sources of bias

We have 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:

- yes;
- no;
- unclear.

(7) Overall risk of bias

We have made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the Handbook (Higgins 2008). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* 'Sensitivity analysis'.

Measures of treatment effect

Dichotomous data

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

Continuous data

For continuous data, we have used the mean difference if outcomes were measured in the same way between trials. We used the standardised mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomised trials

For cluster-randomised trials included in the analyses along with individually randomised trials: Their *standard errors will be* adjusted using the methods described in the Handbook using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), or from another source. If ICCs from other sources were used, we will note this and conduct sensitivity analyses to investigate the effect of variation in ICC. We will synthesise the findings from individually and cluster randomised trials provided that 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.

Dealing with missing data

For included studies, we have noted levels of attrition. We have explored the impact of including studies with high levels of missing data in the overall assessment of treatment by

using sensitivity analysis. We have not included any outcomes in the analyses if there was more than 25% missing data.

For all outcomes we have 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. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We have use the I^2 and T^2 statistics to quantify heterogeneity along with the Chi^2 test for heterogeneity. If we identified substantial heterogeneity (I2 > 30%) we have drawn attention to this in the text.

Assessment of reporting biases

Where we suspected reporting bias (*see* 'Selective reporting bias' above), we attempted to contact study authors asking them to provide missing outcome data. Where this is not possible, and missing data are thought to introduce serious bias, the impact of including such studies in the overall assessment of results may be explored by sensitivity analysis if appropriate**.**

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2008). We will use fixed-effect inverse variance meta-analysis for combining data where trials have examined the same intervention, and the trials' populations and methods are judged sufficiently similar. Where we suspected clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects might differ between trials we have used random-effects meta-analysis.

If substantial heterogeneity was identified in a fixed-effect meta-analysis the analysis was repeated using a random-effects method; and the results from this latter analysis have been presented in the text.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses:

1. By type of supporter (professional versus lay person, or both);
2. By type of support (face-to-face versus telephone support);
3. By timing of support (antenatal and postnatal versus postnatal alone);
4. By whether the support was proactive (schedules contacts) or reactive (women needed to request support);
5. By whether support was offered one-to-one or through group sessions.

We have used primary outcomes only in subgroup analysis.

For fixed-effect meta-analyses we have conducted subgroup analyses classifying whole trials by interaction tests as described by Deeks 2001. For random-effects meta-analyses we have assessed differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals suggesting differences in treatment effect between the subgroups.

Sensitivity analysis

We plan to conduct sensitivity analysis for primary outcomes by study quality, by temporarily removing studies from the analysis where there was poor or unclear allocation concealment to see what impact this would have on the treatment effect. We plan to conduct sensitivity analysis for primary outcomes where cluster randomised trials contributed data; and to vary the ICC to see what impact this would have on results.

Results to date

Description of studies

For this review update, we identified 354 new references. After screening, we selected 14 new trials for inclusion. (Sixty-eight reports have been added to Studies awaiting classification.)