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Irving CB, Saylan M

Irving CB, Saylan M.
Mother and baby units for schizophrenia.
Cochrane Database of Systematic Reviews 2007, Issue 1. Art. No.: CD006333.
DOI: 10.1002/14651858.CD006333.

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[Intervention Review]

Mother and baby units for schizophrenia

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Editorial group: Cochrane Schizophrenia Group.
Publication status and date: Edited (no change to conclusions), published in Issue 11, 2011.
Review content assessed as up-to-date: 13 November 2006.

Citation: Irving CB, Saylan M. Mother and baby units for schizophrenia. *Cochrane Database of Systematic Reviews* 2007, Issue 1. Art. No.: CD006333. DOI: 10.1002/14651858.CD006333.

ABSTRACT

Background

Mother and baby units (MBUs) are recommended, in the UK, as an optimal site for treating post partum psychoses. Naturalistic studies suggest poor outcomes for mothers and their children if admission is needed during the first year after birth, but the evidence for the effectiveness of MBUs in addressing the problems faced by both mothers with mental illness and their babies is unclear.

Objectives

To review the effects of mother and baby units for mothers with schizophrenia or psychoses needing admission during the first year after giving birth, and their children, in comparison to standard care on a ward without a mother and baby unit.

Search methods

We undertook electronic searches of the Cochrane Schizophrenia Group's Register (June 2006).

Selection criteria

We included all randomised clinical trials comparing placement on a mother and baby unit compared to any other standard care without attachment to such a unit.

Data collection and analysis

If data were available we would have independently extracted data and analysed on an intention-to treat basis; calculated the relative risk (RR) and 95% confidence intervals (CI) of homogeneous dichotomous data using a random effects model, and where possible calculated the number needed to treat (NNT); calculated weighted mean differences (WMD) for continuous data.

Main results

Unfortunately, we did not find any relevant studies to include. One non-randomised trial, published in 1961, suggested beneficial effects for those admitted to mother and baby units. For the experimental group, more women were able to care for their baby on their own and experienced fewer early relapses on their return home compared with standard care. Care practices for people with schizophrenia have changed dramatically over the past 40 years and a sensitively designed pragmatic trial is possible and justified.

Authors' conclusions

Mother and bay units are reportedly common in the UK but less common in other countries and rare or non-existent in the developing world. However, there does not appear to be any trial-based evidence for the effectiveness of these units. This lack of data is of concern as descriptive studies have found poor outcomes such as anxious attachment and poor development for children of mothers with schizophrenia and a greater risk of the children being placed under supervised or foster care. Effective care of both mothers and babies during this critical time may be crucial to prevent poor clinical and parenting outcomes. Good, relevant research is urgently needed.

PLAIN LANGUAGE SUMMARY

Mother and baby units for schizophrenia

Post-partum psychosis is a consistent source of new episodes of severe mental illness and its worldwide prevalence has remained unchanged at 1 in 1000 live births over the past 150 years. For some women, admission to hospital is necessary. In the UK special mother and baby units (MBUs) are available in some areas to allow mothers to remain with their babies during treatment. This can help avoid the potential detrimental effects of separation from the mother on the baby and the effect this separation would have on the mother's confidence and capability as a future carer.

While surveys have reported that many women strongly prefer admission to MBUs, there are concerns that admitting a baby to a psychiatric unit for long periods of time may be harmful in terms of institutionalisation of the baby, and the rarer potential risk of physical harm from severely ill mothers. Although MBUs are recommended as the optimal site for treating a perinatal psychosis in the UK, outside of some parts of Australia, Europe, Canada, and New Zealand, they are either virtually non existent or very limited. There is no real clarity in the literature to explain the reasons why there is such a difference in the treatment of women with mental illness around the world.

To assess the efficacy of MBUs we systematically searched for any randomised trials of MBUs compared to standard care. We found no trials involving either mothers suffering from post partum psychosis or severe post natal depression. Anecdotal results from a 1961 trial did suggest a beneficial effect, but non-randomised data from over 40 years ago is difficult to apply to today's care. Such lack of data is of concern as MBUs are expensive to set up and run. If they are to be the 'gold standard' of care for mothers and their babies, their effectiveness needs to validated. Good quality, relevant research is urgently needed.

BACKGROUND

The perinatal period (six weeks after birth) can be a precarious time when mothers may experience a first episode of schizophrenia, or when those already diagnosed with schizophrenia may relapse. Post-partum psychosis, although relatively rare, is a predictable and consistent source of new episodes of severe mental illness, and its worldwide prevalence has remained unchanged at about 1 in 1000 live births over the past 150 years (Kumar 1994, Kendell 1987). A psychotic illness at this time can be severe with hallucinations, delusions and disturbed behaviour relating to the baby. For example, a mother may believe that her baby is deformed or possessed by the devil, leading to a possible risk of harm, including a fatal outcome for the offspring. About one in five women with a post natal disorder need to be admitted to hospital for treatment and of these about 15% are suffering from some form of psychosis. (Hatherley 1979, Cawley 1999)

The idea to admit mothers and babies together was developed over 50 years ago to address the 'twin dangers' of separating mothers with mental illness from their babies; firstly the detrimental effect on the baby and secondly the effect this would have on the mothers confidence as a future carer (Main 1948). Mother and baby units are recommended as the optimal site for treating a perinatal psychosis in the UK (Royal College 2001). The precise nature of a mother and baby unit is variable ranging from a single bed and a nursery attached to an acute ward, up to a regional service with an attached specialised community team. These units are reported to be common in the UK, but some have run into problems in recent years due to under usage (Royal College 1992). They are also rarer in other Western countries and even rarer in the developing world (Kumar 1995).

Limited descriptive evidence suggests that outcomes may be poor

for mothers with schizophrenia and their children. One risk to children of mothers with schizophrenia is that they may have more anxious attachment patterns leading to later developmental problems (Naslund 1984). Children of mothers with schizophrenia are also at risk of losing their mother as a primary carer as their mothers are often considered unable to cope (Howard 2003). This is in spite of the fact that there are no properly validated instruments to assess parenting ability and possible risk to a child whose mother has a diagnosis of schizophrenia (Appleby 1993). Coverdale 1989 reported that 60% of children born to 80 female patients with chronic mental illness were reared by others, most commonly the child's father or adoptive family. This loss of a parenting role might have a detrimental effect on the course of the mother's illness.

Another observed difficulty is that women with schizophrenia tend to disengage at a high rate from mental health services. McNeil 1984 reported that two thirds of mothers did so during pregnancy. The same problem occurs with obstetric services (Sacker 1996). This disengagement might occur because of the awareness of mothers with schizophrenia of the possibility of their child being taken into care. Such disengagement during pregnancy can continue after birth and may worsen outcomes for both mother and child.

Mother and baby units not only care for the mother's psychiatric needs but also help the mother-baby bond to develop. The staff on the unit care for the baby while the mother is acutely psychotic and during recovery they are available to support the mother in parenting and bonding with her baby. Stronger mother-child relationships during the first year of life may not only reduce the risk to the child and the likelihood of the child being taken into care, but can also help relationships in the longer term with consequent better developmental outcomes for the child. There are some suggestions that separation in early infancy can have a direct impact on development, analogous to the effects of early depression (Cogill 1986, Murray 1992). In addition, mother and baby units may be more acceptable to patients and therefore might contribute to better engagement with services, helping to ensure long-term needs are met.

There are, however, some concerns about admitting babies to a psychiatric unit such as the risk of institutionalisation, exposure to multiple carers and potential physical harm from severely deluded mothers (Cawley 1999). It should be noted, however that anecdotal evidence and findings in large surveys suggest the actual incidence of harm to babies in MBUs is very rare (Margison 1982, Buist 1990, Salmon 2004), but no direct comparison with infants left in the care of others during admission has been made. The fact that MBUs are only available in a few Western countries is also, at the moment, not explained (Kumar 1995, Cawley 1999). This may, in part, be related to differences in family structure and preferences, and differences in health resource allocation in different cultures, and, in part, be due to the lack of firm data to support the cost-effectiveness of these units serving as a barrier to implementation (Wisner 1996).

We need to determine whether mother and baby units are able to deliver effective care that not only treats the mother's immediate mental health needs, but helps to develop a good mother-child bond and subsequent parenting ability without putting the baby at any unnecessary risk.

OBJECTIVES

To determine the effects of mother and baby units for mothers with schizophrenia and their children compared to standard care without involvement of such units.

METHODS

Criteria for considering studies for this review

Types of studies

We would have included all relevant randomised controlled trials. Where a trial was described as 'double-blind', but it was implied that the study was randomised, we would have included the trial in a sensitivity analysis. If there had been was no substantive difference within primary outcomes (see 'types of outcome measures') when these 'implied randomisation' studies would have been added, then we would have included these in the final analysis. If there had been a substantive difference, we would only have analysed clearly randomised trials and described the results of the sensitivity analysis in the text. We excluded quasi-randomised studies, such as those allocating by using alternate days of the week.

Types of participants

Mothers with schizophrenia, irrespective of criteria used for diagnosis, assessed as needing admission along with their child, in the first year after child-birth.

Types of interventions

1. Relevant care on mother and baby unit (however defined by authors) at any time during first year after birth of their child.
2. Any other inpatient care that did not involve attachment to a mother and baby unit.

Types of outcome measures

Mother with schizophrenia
1. Death: suicide or natural causes
2. Service utilisation outcomes*
2.1 Hospital readmission
2.2 Days in hospital
2.3 Change in hospital status
3. Clinical response*
3.1 Relapse
3.2 Clinically significant response in global state - as defined by the authors
3.3 Average score/change in global state
3.4 Clinically significant response in mental state - as defined by the authors
3.5 Average score/change in mental state
3.6 Clinically significant response on positive symptoms - as defined by the authors
3.7 Average score/change in positive symptoms
3.8 Clinically significant response on negative symptoms- as defined by the authors
3.9 Average score/change in negative symptoms
4. Service engagement*
4.1 Loosing contact with mental health services
4.2 Leaving the study early
5. Behaviour
5.1 Clinically significant response in behaviour - as defined by each of the studies
5.2 Average score/change in behaviour
5.3 Self harm
5.4 Aggressive behaviour
6. Social functioning
6.1 Clinically significant response in social functioning - as defined by each of the studies
6.2 Average score/change in social functioning
7. Quality of life/satisfaction with care for either recipients of care or carers*
7.1 Significant change in quality of life/satisfaction - as defined by each of the studies
7.2 Average score/change in quality of life/ satisfaction
7.3 Employment status
8. Parenting outcomes*
8.1 Parenting skills
8.2 Quality of relationship with child
8.3 Child taken into care
8.4 Mother with schizophrenia not primary care giver to child
8.5 Unmet needs in mother
8.6 Violence towards child
8.7 Risk of violence to child
Child of mother with schizophrenia
1. Losing contact with services for child*
2. Attachment pattern*
3. Health of child*
3.1 Physical health
3.2 Mental health
3.3 Behaviour
4. Developmental outcomes*
4.1 Attainment of milestones
4.2 Cognitive development
4.3 Emotional development
5. Death
* indicates primary outcomes
We understand that for some outcomes, such as parenting skills, there may be no validated measures. However, it was thought important to include them in order to identify gaps in knowledge which could be of concern to clinicians. As schizophrenia is often a life-long illness, we grouped outcomes according to time periods: short term (up to three months), medium term (three months to one year) and long term (more than one year).

Search methods for identification of studies

1. Electronic search
We searched the Cochrane Schizophrenia Group Trials Register (June 2006) using the phrase:
[((*pregnan* or *pueperal* or *post?partum* or * mother*) in title, abstract, index terms of REFERENCE) or ((female and child and not male in participant) or mother-baby unit in intervention of STUDY)].
This register is compiled by systematic searches of major databases, hand searches and conference proceedings (see Group Module).
2. Reference searching
We sought further studies by searching references of all papers we thought to be relevant to this review.

Data collection and analysis

1. Selection of trials
The principal reviewer CJ inspected all citations of studies identified by searching. MS re-inspected a random 10% sample of the reports in order to ensure reliability of selection. We identified potentially relevant abstracts and ordered and reassessed full papers for inclusion and methodological quality. When disputes arose we attempted resolution by discussion. If doubt remained and further information was necessary to resolve the dilemma, we would not have included the study and added it to the list of those awaiting assessment, pending further information.
2. Assessment of quality
We intended to allocate included trials to three quality categories, as described in the Cochrane Collaboration Handbook (Higgins 2005). We also intended to re-inspect a random 10% sample of trial reports and allocate these trials independently. Had disputes arisen as to which category a trial was allocated, we would have attempted resolution by discussion. Were this not possible, and

further information was required, we would not have entered data into the analyses and the study would have been allocated to the list of those awaiting assessment. We excluded those studies not described as randomised by the authors.

3. Data collection

We intended for CJ to extract data from selected trials. A random 10% selection would have been independently extracted by MS. Had disputes arisen, we would have attempted resolution by discussion. If doubt had remained and further information was necessary to resolve the dilemma, we would not have entered the data but added them to the list of those awaiting assessment, pending further information.

4. Data synthesis

4.1 Data types

We intended to assess outcomes using continuous (for example, average changes on a behaviour scale), categorical (for example, one of three categories on a behaviour scale, such as 'little change', 'moderate change' or 'much change') or dichotomous measures (for example, either 'no important changes' or 'important changes' in a person's behaviour). Currently the RevMan software does not support categorical data so they were dichotomised where possible (see below).

4.2 Incomplete data

With the exception of the outcome of leaving the study early, we planned not to include outcomes from trials where more than 40% of people were not reported in the final analysis. We felt that such a degree of attrition would threaten the validity of any findings.

4.3 Dichotomous data

Where the original authors of the studies gave outcomes such as 'clinically improved' or 'not clinically improved' based on their clinical judgement or predetermined criteria or any scale, this would have been recorded in RevMan. If data was from a rater not clearly stated to be independent then it was to have been included if it did not change the results, otherwise it would have been presented separately with a label 'prone to bias'. Where possible, we would have made efforts to convert relevant categorical or continuous outcome measures to dichotomous data by identifying cut-off points on rating scales and dividing subjects accordingly into groups. This was with the cut-off points 'moderate or severe impairment' for end of study data or 'no better or worse' for change data wherever possible. For continuous data on scales such as the BPRS (Overall1962) cut off points for clinically significant change were preset. The same approach was to have been used for individual data where available. We would have used an intention to treat analysis, where, as long as more than 60% of people completed the study, everyone allocated to the intervention would have been counted whether or not they completed follow-up. It would have been assumed that those who dropped out had a negative outcome, with the exception of death. These data were to be presented in both 'intention to treat' and 'completer 'analyses wherever this affected the results. In cases where the author presented data as 'last result carried forward' for those leaving the study, these data were to be included only if they did not change the overall results.

We would have used relative risk (RR) and 95% confidence intervals (CI) based on the random effects model, as this takes into account any differences between studies even if heterogeneity is not statistically significant, as the preferred statistic for summation. Where possible, we intended to estimate the number needed to treat (NNT).

4.4 Continuous data

4.4.1 In the case of continuous data, we would have presented data for those who completed the trial.

4.4.2 Rating scales: a wide range of instruments is available to measure mental health outcomes. These instruments vary in quality and many are not valid, or even ad hoc. For outcome instruments some minimum standards have to be set: (i) the psychometric properties of the instrument should be described in a peer-reviewed journal; (ii) the instrument should either be: (a) a self-report, or (b) completed by an independent rater or relative (not the therapist); and (iii) the instrument should be a global assessment of an area of functioning.

If it was unclear that scale based data were rated independently of treatment we would have presented the data with a label 'prone to bias'.

4.5 Cluster trials

Studies increasingly employ 'cluster randomisation' (such as randomisation by clinician or practice) but analysis and pooling of clustered data poses problems (Puffer 2003). Firstly, authors often fail to account for intra class correlation in clustered studies, leading to a 'unit of analysis' error (Divine 1992) whereby p values are spuriously low, confidence intervals unduly narrow and statistical significance overestimated. This causes type I errors (Bland 1997, Gulliford 1999).

Where clustering was not accounted for in primary studies, we would have presented the data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. In subsequent versions of this review we would have sought to contact first authors of studies to obtain intra-class correlation co-efficients of their clustered data and to adjust for this using accepted methods (Gulliford 1999). Where clustering has been incorporated into the analysis of primary studies, we would have also presented these data as if from a non-cluster randomised study, but adjusted for the clustering effect.

We have sought statistical advice and have been advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the intraclass correlation co-efficient (ICC) [Design effect = 1+(m-1)*ICC] (Donner 2002). If the ICC was not reported it was assumed to be 0.1 (Ukoumunne 1999).

4.6 Normal data

Mental health continuous data are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data we would have applied the following standards to all data

before inclusion: (i) standard deviations and means were reported in the paper or were obtained from the authors; (ii) If the data were finite measures from, for example 0-100, when the standard deviation was multiplied by two, the result should be less than the mean. Otherwise the mean was unlikely to be an appropriate measure of the centre of the distribution (Altman 1996).
We would have reported non-normally distributed data in 'Other data types' tables. Endpoint scale-derived data are finite, ranging from one score to another. Change data are more problematic and therefore the rule described above does not hold. Although most change scores are likely to be skewed it cannot be proven so we would have presented them in MetaView. Where both endpoint and change were available for the same outcome we would have preferred to present the former.
4.7 Sensitivity analyses
i. Outcomes for intention-to-treat analysis were to have been compared with completer analyses. Where there were differences these were to have been either reported or presented graphically.
ii. Outcomes for studies excluded as belonging to quality category C would have been compared with outcomes for all included studies.
5. Heterogeneity
We intended to assess heterogeneity by visual inspection of the graphs and would have supplemented this procedure using the I-squared statistic. This measure provides an estimate of the percentage of variability due to heterogeneity rather than chance alone. Where the I-squared estimate was greater than or equal to 75%, we would have interpreted this as indicating the presence of high levels of heterogeneity (Higgins 2003). In such cases we would have investigated the reasons for heterogeneity.
6. Addressing publication bias
We would have entered data from all identified and selected trials into a funnel graph (trial effect versus trial size) in an attempt to investigate overt publication bias.
7. Tables and figures
Where possible, we intended to enter data into RevMan so the area to the left of the line of no effect indicated a favourable outcome for the mother and baby unit.

RESULTS

Description of studies

See: Characteristics of excluded studies.
1. Excluded studies
We did find one report comparing mother and baby units with standard care. We had to exclude this important study as it did not randomise comparison groups. Baker 1961 compared 20 mothers treated on a mother and baby unit with 20 mothers treated on an acute admission ward (baby not admitted with mother). Another comparison within the trial involved mothers on the mother and baby unit who were randomised to receive ECT or chlorpromazine. Considering how few the data are for this review, this old study must be seen as ground-breaking.
2. Awaiting assessment
There are no studies awaiting assessment
3. Ongoing studies
We are not aware of any ongoing studies.
4. Included studies
We found no studies that attempted to assess the effectiveness of mother and baby units by means of a randomised controlled trial.

Risk of bias in included studies

No studies were included in this 2006 version of the review.

Effects of interventions

1. The search
Our search identified 44 references, but most were obviously not relevant to this review and it would have done no service to the reader to include them here.
2. The one excluded trial (Baker 1961).
All mothers on the mother and baby unit were reported as being able to take full care of their baby on their return home. Just over half of the mothers in the standard care group were able to care for their children once home (13/20). The mother and baby unit group were reported as being more seriously ill on admission but were discharged with fewer symptoms. The average duration of stay was ten weeks on the mother and baby unit and sixteen weeks on the admission ward. Baker 1961 also reported a lower early relapse rate (one third less) in mothers discharged from the mother and baby unit (duration of follow up not reported).

DISCUSSION

1. The search

The search of the Cochrane Schizophrenia Group's Register, based on detailed and regular searches of a variety of databases, conference proceedings and unpublished sources, was planned to be highly sensitive. Nevertheless, some relevant publications may have been missed, although such a study would be of such importance and rarity that it would be likely to be disseminated widely. Using only the Cochrane register would have selected out any other non-randomised studies that could have been of interest.

2. General

2.1 Information from non-randomised studies

For the reasons above this work does not represent a good overview of non-randomised data. There could be other such studies of which we are unaware. We feel that such a review is needed and would be informative.

The only comparative trial identified by our search, Baker 1961, is pioneering, but of uncertain relevance. It is not randomised and took place over 40 years ago. Diagnostic practices have changed considerably and it is possible that several mothers in that study would not be diagnosed to have schizophrenia by modern criteria. For example, 75% of mothers were experiencing their first episode of illness. For women ill at this time there are real problems making confident, definitive diagnoses. A high percentage of patients with puerperal psychosis are later found to have bipolar disorder (Chaudron 2003).

2.2 Information from randomised trials

By setting the methodological entry criteria high, at randomised controlled trial, we could have been too exacting. We are trying not to underestimate the enormous difficulties organising and undertaking a randomised trial in this sensitive area. Any research is likely to be fraught with difficulties and ethical dilemmas. It does remain, however, of concern, that there are no randomised trials evaluating the effects of mother and baby units as their numbers increase in Western countries. Currently, we are unable to assess whether this significant investment improves outcomes for this vulnerable group. It is not difficult to see how, in the likely context of rationing of care, that randomisation to a special unit for mothers and their babies could be undertaken in order to ensure equity of provision. The control group would have to be provided the highest standard of care, but not from within a specialist unit.

AUTHORS' CONCLUSIONS

Implications for practice

1. For parents of a new baby

We did not find reliable objective evidence for the efficacy of mother and baby units. These findings are similar to other reviews and surveys of MBUs that have also commented on the lack of hard evidence to justify their existence (Cawley 1999, Kumar 1995). Although nearly all women in relevant surveys wish to use a MBU rather than a standard ward (Margison 1982, Kumar 1995; Neil 2006) it is, at the moment unclear if they have any beneficial effect in terms of mother recovery, risk to infant and/or development of the mother-child bond, compared with standard care. Although mother and baby units have been recommended as the optimal site for treating a perinatal psychosis in the UK (Royal College 2001) we are unable to comment on whether such units deliver expected outcomes and justify their cost.

2. For clinicians

In the very difficult circumstances of needing to provide care for a mother with serious and often acute mental illness, along with her baby, the clinician will be striving to provide the very best and most sensitive care to the needs of everyone involved. In a situation where provision is constrained, by, for example, number of available beds in a specialist unit, it may only be possible for the psychiatric services to be fair to several needy families, by giving the highest possible care to everyone from within a randomised study. In this way some women and their families would be cared for within a special unit and others within parallel mental health care facilities that are not specifically for mothers with their babies.

3. For policy makers and managers

Units for mentally ill mothers and their babies are expensive and their effects benefits over other packages of care, uncertain. That such units are preferred by patients is, however, an important but not sufficient reason for unevaluated investment. It would seem, if such units are to be constructed and staff recruited that the start-up phase, when one older package of care is being phased out in favour of the new units, affords an opportunity for evaluation.

Implications for research

1. General

1.1 Another review

We do think that a systematic review of controlled studies is justified. Randomising admission to mother and baby units is really problematic so it is understandable that no studies exist. We have identified one old controlled trial (Baker 1961) and there may be others that we have failed to find. These could inform modern practice or study design.

1.2 Reporting

In general, all future trials should follow CONSORT guidelines (Begg 1996, Moher 2001). This would help clarify methodology and many outcomes. Failure to comply results in both loss of data and confusion about the validity the results, neither of which help clinicians, patients of managers. Since the unit of randomisation in future trials would be mother and baby units versus standard care, it is crucial that these trials follow the extension of the CONSORT statement for cluster randomised trials (Campbell 2004a). Investigators would then receive guidance on correct ways to calculate the required sample size, to randomise to minimise bias, to analyse the data, and to report the intracluster correlation coefficient, all of which pose problems of particular relevance to cluster randomised trials (Puffer 2003). Additional issues with cluster randomised trials include the potential for recruitment biases since blinding these trials is more difficult as randomisation would occur at the start of the trial. Ethical issues resulting from cluster leaders having to consent to the trial on behalf of the potential cluster members would also need to be overcome (Campbell 2004b).

The flow diagram for these trial reports should report both how the cluster as well as the individuals progress through the trial. Intention-to-treat analysis should be performed on all outcomes and all trial data made easily accessible. A minimal requirement should be that all data should, at least, be presented as numbers. In addition, continuous data should be presented with means, standard deviations (or standard errors) and the number of participants. Data from graphs, 'p' values of differences and statements of significant or non-significant differences are of limited value.

2. Specific

We acknowledge that undertaking a randomised controlled trial of mother and baby units will be difficult, but, learning from older studies such as Baker 1961, not impossible. We suggest a design in Table 1.

2.1 Methods

Trials would be impossible to fully blind but single blinding may be achievable. In order to achieve useful numbers a multi-centre study would be needed. This could introduce problems with variation in both intervention and control provision.

2.2 Participants

It would be important to consider variation in diagnostic criteria across different units (Cawley 1999, Kumar 1995). For good direct comparisons clear and uniform diagnostic criteria across units would be helpful.

2.3 Interventions

A multicentre study in this difficult area would, out of necessity have considerable variation in provision in both the intervention and standard care groups. Both interventions should be of the highest and safest standards that the local services can provide, running in parallel and provided equitably for those in need.

2.4 Outcomes

For studies of MBUs there is not just the mother's health to consider but also that on the baby and wider family. Reports of outcomes of admission to mother and baby units consistently indicate that mothers with schizophrenia are characterized as having more complex clinical and psychosocial problems and are considerably more likely to experience all types of poor parenting outcomes, compared with mothers with affective disorders (Kumar 1995, Freudenthal 2004, Salmon 2003, Salmon 2004, Abel 2005). Mothers with schizophrenia, in these reports, were more likely to be behaviourally disturbed, have more social and financial problems, be single mothers or have partners with psychiatric disturbances. Models of interventions in future trials involving MBU admission for mothers with schizophrenia should therefore be tailored to match the needs of these mothers, including targeting socioeconomic difficulties and detection and treatment of psychiatric disorders in their partners.

Finally we suggest the primary outcome measures used in any future trials should follow those used in this review, focusing primarily on clinical response, service utilisation and engagement (both mother and child), parenting outcomes, attachment and development. Long term follow up is important, particularly for outcomes concerning the children and the overall confidence of women in their roles as mothers.

ACKNOWLEDGEMENTS

We would like to thank Clive Adams, Tessa Grant and Judith Wright of the Cochrane Schizophrenia Group, UK for their invaluable support and help. Alec Sultana instigated this review but unfortunately the Cochrane Schizophrenia Group has been unable to contact Alex. His contribution in getting this review started, nevertheless, was considerable.

REFERENCES

References to studies excluded from this review

Baker 1961 ***{published data only}***

* Baker AA, Morison M, Game JA, Thorpe JG. Admitting schizophrenic mothers with their babies. *Lancet* 1961;**2**: 237–9.

Additional references

Abel 2005

Abel KM, Webb RT, Salmon MP, Wan MW, Appleby L. Prevalence and predictors of parenting outcomes in a cohort of mothers with schizophrenia admitted for joint mother and baby psychiatric care in England. *Journal of Clinical Psychiatry* 2005;**66**:781–9.

Altman 1996

Altman DG, Bland JM. Detecting skewness from summary information. *British Medical Journal* 1996;**313**:1200.

Appleby 1993

Appleby L, Dickens C. Mothering skills of women with mental illness. *British Medical Journal* 1993;**306**:348–9.

Begg 1996

Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF. Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996;**276**(8): 637–9.

Bland 1997
Bland JM. Statistics notes. Trials randomised in clusters. *BMJ* 1997;**315**:600.

Buist 1990
Buist A, Dennerstein L, Burrows DG. Review of a mother and baby unit in a psychiatric hospital. *Australian and New Zealand Journal of Psychiatry* 1990;**24**:101–8.

Campbell 2004a
Campbell MK, Elbourne DR, Altman DG for the CONSORT Group. The CONSORT statement: extension to cluster randomised trials. *BMJ* 2004;**328**:702–8.

Campbell 2004b
Campbell MJ. Extending CONSORT to include cluster trials. *BMJ* 2004;**328**:654–5.

Cawley 1999
Cawley S, Griffiths L, Brier G. Who needs a mother and baby unit?. *Nursing Standard* 1999;**13**:33–6.

Chaudron 2003
Chaudron LH, Pies RW. The relationship between postpartum psychosis and bipolar disorder: a review. *Journal of Clinical Psychiatry* 2003;**64**:1284–92.

Cogill 1986
Cogill S, Caplan HL, Alexandra H, Robson KM, Kumar R. Impact of maternal postnatal depression on cognitive development of young children. *British Medical Journal* 1986;**292**:1165–7.

Coverdale 1989
Coverdale JH, Aruffo JA. Family planning needs of female chronic psychiatric patients. *American Journal of Psychiatry* 1989;**146**:1489–91.

Divine 1992
Divine GW, Brown JT, Frazier LM. The unit of analysis error in studies about physicians' patient care behavior. *Journal of General Internal Medicine* 1992;**7**(6):623–9.

Donner 2002
Donner A, Klar N. Issues in the meta-analysis of cluster randomized trials. *Statistics in Medicine* 2002;**21**:2971–80.

Freudenthal 2004
Glangeaud-Freudenthal NM. Mother-Baby psychiatric units (MBUs): national data collection in France and in Belgium (1999-2000). *Archives of Womens Mental Health* 2004;**7**:59–64.

Gulliford 1999
Gulliford MC. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the Health Survey for England 1994. *American Journal of Epidemiology* 1999;**149**: 876-83 876-83.

Hatherley 1979
Hatherley LI, et al.Psychiatric disorders in obstetrics. *Medical Journal of Australia* 1979;**2**:399–401.

Higgins 2005
Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions 4.2.5 [updated May 2005]. In: Higgins JPT, Green S editor(s). *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd., 2005.

Howard 2003
Howard L, Shah N, Salmon M, Appleby L. Predictors of social services supervision of babies of mothers with mental illness after admission to a psychiatric mother and baby unit. *Social Psychiatry and Psychiatric Epidemiology* 2003; **38**:450–5.

Kendell 1987
Kendell RE, Chalmers JC, Platz C. Epidemiology of puerperal psychosis. *British Journal of Psychiatry* 1987;**144**: 35–47.

Kumar 1994
Kumar R, Hipwell AE. Implications for the infant of maternal puerperal psychiatric disorders. In: Rutter M editor(s). *Child and Adolescent Psychiatry*. 3rd Edition. Oxford: Blackwell, 1994.

Kumar 1995
Kumar R, Marks M, Platz, Yoshida K. Clinical survey of a psychiatric mother and baby unit: characteristics of 100 consecutive admissions. *Journal of Affective Disorders* 1995; **33**:11–22.

Main 1948
Main T. Mothers and children in psychiatric hospital. *Lancet* 1948;**11**:845.

Margison 1982
Margison F, Brockington IF. Psychiatric mother and baby units. In: Brockington IF, Kumar R editor(s). *Motherhood and mental illness*. London: Academic Press, 1982:223–7.

McNeil 1984
Mc Neil TF, Kaij L, Malmquist-Larsson A. Women with non-organic psychosis: mental disturbance during pregnancy. *Acta Psychiatrica Scandinavica* 1984;**70**:127–39.

Moher 2001
Moher D, Schulz KF, Altman DG, for the CONSORT Group. Revised recommendations for improving the quality of reports of parallel group randomized trials 2001. *The Lancet* 2001;**357**:1191–4.

Murray 1992
Murray L. The impact of postnatal depression on infancy development. *Journal of Child Psychiatry* 1992;**33**:543–61.

Naslund 1984
Naslund B, Persson-Blennow J, McNeil T. Offspring of women with non-organic psychosis: infant attachment to mother at one year of age. *Acta Psychiatrica Scandinavica* 1984;**69**:231–341.

Neil 2006
Neil S, Sanderson H, Wieck A. A satisfaction survey of women admitted to a Psychiatric Mother and Baby Unit in the northwest of England. *Archives of Womens Mental Health* 2006;**9**:109–12.

Overall1962
Overall JE, Gorham DR. The Brief Psychiatric Rating Scale. *Psychological Reports* 1962;**10**:799–812.

Puffer 2003
Puffer S, Torgerson D, Watson J. Evidence for risk of bias in cluster randomised trials: review of recent trials published in three general medical journals. *BMJ* 2003;**327**:785–9.

Royal College 1992
Royal College of Psychiatrists. Report of the General Psychiatry Section Working Party on Post-Natal Mental Illness. *Psychiatric Bulletin* 1992;**16**:519–22.

Royal College 2001
Royal College of Psychiatrists. Perinatal Maternal Mental Health Services. Recommendations for Provision of Services for Childbearing Women. *Psychiatric Bulletin* 2001;**25**:278.

Sacker 1996
Sacker A, Done DJ, Crow TJ. Obstetric complications in children born to parents with schizophrenia. *Psychological Medicine* 1996;**26**:279–87.

Salmon 2003
Salmon M, Abel K, Cordingley L, Friedman T, Appleby L. Clinical and parenting skills outcomes following joint mother-baby psychiatric admission. *Australia and New Zealand Journal of Psychiatry* 2003;**37**:556–62.

Salmon 2004
Salmon MP, Abel K, Webb R, Warburton AL, Appleby L. A national audit of joint mother and baby admissions to UK psychiatric hospitals: an overview of findings. *Archives of Womens Mental Health* 2004;**7**:65–70.

Ukoumunne 1999
Ukoumunne OC, Gulliford MC, Chinn S, Sterne JAC, Burney PGJ. Methods for evaluating area-wide and organistation-based intervention in health and health care: a systematic review. *Health Technology Assessment* 1999;**3**(5): 1–75.

Wisner 1996
Wisner KL, Jennings KD, Conley B. Clinical dilemmas due to the lack of inpatient mother-baby units. *International Journal of Psychiatry in Medicine* 1996;**26**:479–93.

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Baker 1961	Allocation: not randomised.

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Suggested design for trial

Methods	Participants	Interventions	Outcomes	Notes
Allocation: centralised sequence generation with table of random numbers or computer generated code, stratified by severity of illness, sequence concealed till interventions assigned. Blinding: those recruiting and assigning participants, those assessing outcomes, all blind to allocated group. Duration: minimum of 1 year.	Diagnosis: schizophrenia (DSM IV) , subtypes and schizoaffective disorder included and numbers in each category clearly reported. N=300.* Age: adults. Sex: men and women. Setting: mulitcentre; inpatients and community. History: baseline score on scale such as BPRS or PANSS, stratified by cut-off points into moderate and severe illness	1. In-patient mother and baby unit: Relevant care on mother and baby unit at any time during first year after birth of their child 2. Standard care: Any other inpatient care that did not involve attachment to a mother and baby unit.	Qualtiy of life: healthy days. Service outcomes: days in hospital, time attending psychiatric outpatient clinic. Satisfaction with care: patients/carers. Global state**: CGI.*** Mental state: CGI, relapse** including behaviour. Functioning: mothers**, babies** and wider families health, confidence in parenting skills**, attachment behaviour, engagement with services, leaving the study early, living independently. Adverse effects: baby and mothers development, mortality. Cognitive function. Economic outcomes: cost-effectiveness and cost-benefit.	* size of study to detect a 10% difference in improvement with 80% certainity. ** Primary outcome. *** If scales are used to measure outcome then there should be binary cut off points, defined before study start, of clinically important improvement

WHAT'S NEW

Last assessed as up-to-date: 13 November 2006.

Date	Event	Description
5 October 2011	Amended	Contact details updated.

HISTORY

Review first published: Issue 1, 2007

Date	Event	Description
4 August 2010	Amended	Contact details updated.
14 April 2010	Amended	Contact details updated.
5 August 2009	Amended	Contact details updated.
23 April 2008	Amended	Converted to new review format.
14 November 2006	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Claire Joy (CJ) - writing of review.

Mete Saylan (MS) - random 10% checks of papers for inclusion/exclusion, searching, help and advice with writing of review.

DECLARATIONS OF INTEREST

None.

SOURCES OF SUPPORT

Internal sources

- Department of Health, UK.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Child of Impaired Parents; *Hospitalization; *Maternal-Child Health Centers; Infant, Newborn; Psychotic Disorders [therapy]; Puerperal Disorders [*therapy]; Schizophrenia [*therapy]

MeSH check words

Female; Humans; Infant