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Intervening to reduce depression after birth: A systematic review of the randomized trials

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A systematic review and meta-analysis of randomized trials of nonpharmaceutical and nonhormonal interventions to reduce postnatal depression was carried out to summarize the effectiveness of interventions grouped in terms of the nature and timing of the intervention and whether the trial population was universal, selective, or indicated.

Keywords: Depression, Postnatal care, Randomized controlled trial, Review literature, Maternal welfare

Postnatal depression—nonpsychotic depressive illness—is a major public health problem affecting approximately one in seven women after childbirth. Postnatal depression is neither minor, nor is it usually self-limiting (25;77;89). It is commonly associated with symptoms of anxiety (94). The prevalence of postnatal depression ranges from 10 to 18 percent of women in population-based studies extended through the first six months after birth. A recent meta-analysis by O'Hara and Swain (81) of fifty-nine community studies carried out in the first six weeks after birth reported the pooled prevalence as 13 percent. Postnatal depression is much more prevalent than this in socially and economically disadvantaged populations, as described by Cooper and colleagues in South Africa (22), Patel and colleagues in Goa (84), Hobfoil and colleagues in inner-city U.S. women (52), and Wolf and colleagues in three Latin American samples (103). The prevalence of depression after birth and during pregnancy is similar (34), and although some of the associated risk factors differ across those depressed only in pregnancy, those depressed only postpartum, and those depressed at both times (43), there is considerable overlap in risk factors. Thus, there is a case for considering the problem as perinatal rather than postnatal depression. However, there is a threefold increase in the onset of depression in the first five weeks after birth (26). There is consistent evidence that women who have had one such experience are at increased risk of its occurrence after a subsequent birth (7;102).

Apart from the adverse consequences for women themselves of becoming depressed when they are going through demanding physical and social changes and a major life transition there are additional concerns about the possible negative impact of maternal depression on the relationship between mother and child and on the child's emotional, behavioral, and cognitive development (21;48;78;79), especially in the presence of any other morbidity (17).

Postnatal depressive symptoms are essentially the same as those of depression occurring at other times. Other commonalities are those relating to help-seeking. Most women experiencing depression after birth do not seek professional help, and up to half of them do not seek help from friends and family either (68;89). Women often have many contacts with general practitioners (GPs; 45), and other primary-care practitioners such as health visitors or maternal and child

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health nurses (29), and to a lesser extent with obstetricians or pediatricians in the first year after birth. Despite these established relationships, women are relatively unwilling to disclose many common physical and emotional problems which begin after, or are aggravated by, birth (12;37;66). There is also consistent evidence that professionals' recognition of maternal depression in primary care, including recognition within child health consultations is poor (e.g., 6;33). There is some evidence among GPs of reluctance to identify depression and other maternal postpartum problems for which no simple standard care can be offered (46). Depression after birth is commoner among women with physical health problems (13).

Given the prevalence of postnatal depression, its considerable morbidity, and the likelihood of longer-term effects on children, it is very important to summarize the best current evidence on prevention and treatment, to identify gaps in the research available, and to highlight future research priorities. This was the rationale for carrying out a systematic review of the randomized trials.

PREVIOUS SYSTEMATIC REVIEWS OF INTERVENTIONS TO REDUCE DEPRESSION AFTER BIRTH

Five systematic reviews of strategies for reducing the prevalence of postnatal depression are listed in the Cochrane Library. The review by Lawrie and coworkers concludes that there is no place for synthetic progestogens in the prevention or treatment of postnatal depression and that long-acting progestogen contraceptives should be used with caution in the postnatal period, because one at least is associated with an increased risk of postnatal depression. They report that oestrogen therapy may be of modest value at a late stage of severe postnatal depression, and its use has not been evaluated in the prevention of recurrent postnatal depression (62). The Cochrane Review of antidepressants by Hoffbrand and colleagues draws attention to the absence of trials carried out in the perinatal period (56), with the exception of one trial with a factorial design carried out by Appleby and coworkers (2), discussed later in this current review. Women in that trial were allocated to fluoxetine or placebo and to one or six sessions of cognitive-behavioral counseling. The third systematic review by Granger and Underwood, listed in the Cochrane Library's Database of Reviews of Effectiveness, concludes that there is no evidence that progesterone reduces postnatal depression (42). Another Cochrane Review, by Ray and Hodnett (86), is restricted to two trials of "caregiver support" after birth, and those two trials are included in this review. Hodnett's Cochrane Review of support in pregnancy for women at increased risk (of having a baby of low birthweight) and support in labor includes data on several postnatal psychological outcomes but no formal measures of depression (53;54). The Cochrane Library includes a Protocol for a review of postnatal interventions by Dennis and Kavanagh (27), but this review excludes trials with psychiatrist- or psychologist-led interventions. An extensive review of strategies for reducing depression by Boath and Henshaw (10), not restricted to randomized or controlled interventions, published in 2001 was an important ancillary source for this current review, but as its focus was on psychological interventions, it did not include all the relevant trials.

The aim of this systematic review is to summarize the effectiveness of interventions, tested in randomized or quasirandomized trials, to reduce maternal depression after birth. These interventions include a wide range of psychological, supportive, and educational strategies, implemented on an individual basis or in groups. Broader interventions within maternal and perinatal care such as enhanced continuity of care are included, as are interventions with the mother and her partner, or the mother and the infant. The trials excluded from this review are those of pharmaceutical and hormonal interventions described above (42;56;62), and two recent trials, one showing that thyroxine treatment does not prevent postnatal depression in thyroid-antibody-positive women (47), the other showing no benefit of docosahexanoic acid supplementation on postpartum depression (64). It has been common practice to set aside questions about possible differences between women with depression appearing for the first time after birth, women who had depression during pregnancy, and those with chronic or recurrent depression, in the implementation of these interventions and that convention will be followed here.

METHODS

Search Strategy for the Identification of Studies

PUBMED, EMBASE, PsychInfo, CINAHL, the Cochrane Database of Systematic Reviews, and the Cochrane Collaboration Controlled Trials Register were searched from 1980 (or their initiation if that was later) to March 2003, using as search terms antenatal, postnatal, postpartum, pregnancy, mood disorder, and depression, restricting papers to English or French. All papers coded as controlled trials, clinical trials, or randomized controlled trials were read. Other abstracts were retrieved and followed up by reading the paper, if there was any possibility that the study had been a controlled trial.

Additional searches used the reference lists of published papers and chapters, and recent proceedings of the Marcé Society. Studies listed in the UK National Research Register under "postnatal depression" were followed up to identify completed trials available as conference abstracts and to check the completeness of the search strategy.

References to trials, other than those which report the main study outcomes, have been included where they describe the development or process evaluation of the intervention or give additional details of the trial design and analysis.

Criteria for Study Selection

Study design: randomized controlled trials, and quasirandomized trials involving alternate allocation or assignment by time period.

Participants: pregnant women, women in labor, or women in the year after birth.

Settings: hospitals, primary care, and community settings.

Types of interventions: any nonpharmaceutical, nonhormonal intervention, including counseling (all types), educational or psychoeducational strategies, the provision of practical or emotional support; and interpersonal, cognitive-behavioral, or psychodynamic therapy. Interventions that involved the woman's partner and those that involved the infant were included if reducing maternal depression was a primary or secondary aim. Interventions involving the reorganization of maternity care in pregnancy, labor, or the postnatal period were included if reducing maternal depression was a primary or secondary aim. There were no exclusions based on the professional group providing the intervention. Interventions provided to individuals and those provided within groups have both been included.

Types of outcome measures: depression characterized as "caseness" or "probable caseness" by diagnostic interview or other standard measure, mean scores on validated scales for assessing depression, and changes in scores preintervention to postintervention.

Exclusion criteria: controlled trials that were neither randomized nor quasirandomized (e.g., 23) and trials in which the participants had been referred after earlier unsuccessful treatment for postnatal depression (e.g., the pilot study of Meager and Milgrom [70]).

Classification of Included Studies

Some interventions were designed to be offered to all pregnant women, or all women in labor or all women after birth. They were potentially *universal*. Some were designed to be offered to women at increased risk of becoming depressed: *selective* women were offered the intervention, a process that involved some form of screening to decide who was at-risk. The last group, *indicated* interventions, were designed for women who had been identified as depressed or probably depressed. This designation follows the Institute of Medicine classification of mental health interventions by Mrazek and Haggerty (74). The other dimension of the classification was whether the intervention began in pregnancy, in labor or after birth, because this has implications in terms of how it could be incorporated into health services.

Data Analysis

Data were abstracted systematically from the papers by JL and tabulated in a predesigned format. The analysis of outcome data was carried out using Comprehensive Meta-analysis (11) to calculate the relative risk of depression and its 95 percent confidence interval (CI), in the intervention and comparison arms of the trial, for trials where depression or probable depression was the end point. Although the criteria for depression or probable depression varied among the trials the end point definitions and methods of assessment were identical across treatment groups within each trial. For all comparisons, this meta-analysis aggregated these in-trial comparisons across studies. Meta-analyses were carried out with fixed effects and random effects models, testing for heterogeneity.

RESULTS

Table 1 summarizes the study population and the interventions. More detailed information about the setting and the country, number of participants, participation proportions, method of selection for selective and indicated interventions, method of randomization, attrition, participation in the intervention, loss to follow-up and the interventions themselves are summarized from data in the original publications on the following Web site: www.latrobe/csmch/prism.

There are five trials of *universal antenatal* interventions. The first was a group intervention, developed by Gordon and Gordon with a strong didactic and advisory focus, implemented within a childbirth education program (39–41). Antenatal classes rather than individual women were randomized, with stratification for partner attendance. The second universal intervention, implemented in three trials, one in the Scotland (88;95) and two in Australia (8;9;96;97), involved a comparison between standard maternal and perinatal hospital and community care through the whole pregnancy, labor, and postnatal period with new programs of team midwifery care planned to enhance continuity of care and to increase the chance that there would be continuity of carer as well. The third universal intervention was a multifaceted psychoeducational intervention about perinatal depression developed for women having their first child, delivered on a one-to-one basis by an experienced midwife (49).

Characteristics of the seven *selective antenatal* interventions, all of which followed screening to select women at increased risk of postnatal depression, are summarized next. Elliott and colleagues (31;32;63) carried out the first controlled trial, a psychoeducational group intervention to normalize the experience and empower participants. The intervention was implemented in groups in four other trials (Buist [16], Brugha and colleagues [14;15;99;100], Stamp and colleagues [92;93], Zlotnick and colleagues [105]). Although they had many features in common, these trials differed in the number of sessions provided, the theoretical basis for the intervention, and the balance between education, support, problem-solving, and the acquisition of skills. Attendance at the groups also varied as did the completeness of follow-up. The other two trials were implemented on a one-to-one basis. One, carried out by Marks and colleagues (65) involved enhanced continuity of midwifery care, similar to

Table 1. Interventions to Reduce Postnatal Depression Grouped by Timing and Participants

1st Author, date, reference	Intervention
	Universal antenatal
Gordon, 1960 (39-41)	Group intervention, two additional antenatal classes on social and psychological aspects of being a new mother, with 12 key messages.
Shields, 1997 (88;95)	Introduction of midwife-managed care teams to increase continuity of care, responsible for antenatal, intrapartum, and postnatal care, compared with standard hospital maternity care.
Waldenström, 1999, 2000 (96-97)	Introduction of team midwife care from a team of eight midwives, recruited from midwifery staff (volunteers), providing antenatal and intrapartum care in collaboration with medical staff, compared with standard hospital maternity care.
Biro, 1999 (8-9)	Introduction of team midwife care from a team of seven midwives providing antenatal, intrapartum, and postpartum care in collaboration with medical staff and other members of the health team.
Hayes, 2001 (49)	Psychoeducational intervention (package of information for women, partners, and extended family, audiotape of one women's experiences of depression and recovery) delivered by an experienced midwife, at home or in antenatal clinic.
	Selective antenatal interventions
Elliott, 1988, 2000 (31-32; 63)	Psychoeducational group intervention, 11 sessions, led by a psychologist and Health Visitor, focus on normalising and empowering
Stamp, 1995 (92-93)	Intervention modelled on that of Elliott & Leverton (above), but with partners invited to all sessions, two sessions in pregnancy, one six months after birth
Buist, 1998 (16)	Psychoeducational group intervention, 10 sessions, led by a midwife/childbirth educator and a psychologist/-nurse, focus on emotional issues, the reality of parenting, didactic teaching, interactive group work, films, and experiential exercises
Brugha, 2000 (14-15; 99-100)	Group intervention, six structured 2-hour, weekly classes, + initial meeting with women and partner and reunion class 8 weeks after birth, focus on acknowledgement of social and emotional problems of pregnancy; information about postnatal depression; learning to develop, use, and maintain support skills; learning and practising problem-solving skills; exploration of unhelpful thought and beliefs about pregnancy and motherhood
Zlotnick, 2000 (105)	Group intervention, four weekly 1-hour sessions, based in interpersonal therapy, psychoeducation on "baby blues" and depression, role transitions and goals, setting goals, developing supports, identifying potential conflicts and skills for resolving them
Webster, 2003 (98)	Provision of educational material about postnatal depression, discussion with women of their increased risk, letter sent to [subject to her consent] woman's family physician and Child Health Nurse, offer of referral to psychiatrist or social worker, case-management review
Marks, 2002 (65)	Specialist team of six midwives, including a named individual midwife, providing continuity of care, social support, enhanced likelihood of detection of early symptoms, and rapid referral for assessment and treatment of mental health problems
	Indicated antenatal interventions
Spinelli, 2003 (91)	A 16-week, bilingual intervention comparing individual interpersonal psychotherapy with individual parent education sessions, also offered over 16 weeks
	Interventions during labor
Hoffman, 1992 (57)	Additional support through labor from a "doula" (a lay companion trained through the project) vs. routine obstetric care
Wolman, 1993; Nikodem, 1998 (80;104)	Additional support through labor and birth from a lay companion (no special training) vs. obstetric care in a setting with limited availability of nursing staff
Gordon, 1999 (38)	Additional support through labor from a doula (a lay companion who had attended a community-based training program) vs. usual care
Hodnett, 2002 (55)	Continuous support through labor by a trained labor support nurse compared with usual care by a nurse not trained in labor support.
	Universal postnatal interventions
Gunn, 1998 (44)	Referral for an early postnatal check-up with a general practitioner 1 week after leaving hospital compared with the standard 6-week check-up
Lavender, 1998 (61)	"Listening and discussion" visit by a midwife on the 2nd day after birth in the postnatal ward, with medical record available for clarification, compared with standard postnatal care
Priest, 2003 (85)	Individual standardised debriefing session based on the principles of critical incident stress debriefing carried out by a midwife trained to deliver the intervention within 72 hours of delivery, compared with usual postnatal care
Morrell, 2000 (72-73)	Ten home visits in the 1st month, up to 3 hours duration, offering effective practical and emotional support, including helping the mother to regain confidence and reinforcing midwifery advice on infant feeding from a community postnatal support worker, in addition to standard community midwifery care, compared with standard community midwifery care

Table 1. Continued

MacArthur, 2002 (67)	Midwife-led community postnatal care for 3 months after birth, following training in the use of symptom checklists and the Edinburgh Postnatal Depression Scale, to identify health needs, with evidence-based guidelines for the management of identified issues compared with routine postnatal care
Reid, 2002 (87)	Two interventions: a self-help manual, and an invitation to a support group were offered by mail 2 weeks after birth. Women were offered either one or both or neither in a factorial design
	Selective postnatal interventions
Armstrong 1999, 2000 (3-4)	Structured program of child health nurse home visits, following specific training and following a manual, weekly for 6 weeks, 2-weekly until 12 weeks, monthly to 6 months; brief social work intervention at home if required. Program focus was to establish a relationship of trust with the infant's family, enhance parenting self-esteem and confidence by positive reinforcement, provide anticipatory guidance for normal child development problems, promote preventive child health care, and facilitate access to appropriate community services.
Small 2000 (90)	Offer of debriefing by one of two skilled and experienced midwives during the postnatal hospital stay compared with routine postoperative postnatal care; leaflet about practical sources of help after giving birth provided to women in both arms of the trial.
Chabrol (A) 2002 (18-19)	One counselling session integrating supportive, educational, and cognitive-behavioural components provided by one of five female Master's level psychology students, given didactic and clinical training, as well as weekly supervision.
Dennis 2003 (28)	Telephone-based peer support from a mother who had experienced (and recovered from) postnatal depression and attended a 4-hour training session.
	Indicated postnatal interventions
Holden 1989 (58)	Individual counselling in their own homes for 8 weekly, 1 hour sessions by Health Visitors who had received brief training in Rogerian (non-directive) counselling, compared with routine primary care.
Fleming 1992 (36)	Groups of 6 to 8 mothers, with 6- to 8-week old infants, met for 2 hours weekly for 8 weeks led by two psychologists; focus to bring women into contact with other women having similar experiences, to share problems and conflicts, and talk about solutions; unstructured format, with a different theme for each Session Mail-only intervention: a short script or scene was sent each week for 8 weeks, adapted from verbatim transcripts of the sessions above, with a set of questions.
Wickberg 1996 (101)	Individual nondirective counselling for six weekly, 1-hour sessions from Child Health Nurses who had received 4 half-day training sessions, compared with routine care with offer of visiting the clinic whenever needed.
Field 1996 (35)	One of two interventions. Massage: 30-minute massage/day on 2 consecutive days of the week for 5 consecutive weeks, administered by trained massage therapists, at the same time of day. Relaxation: same amount of time spent in relaxation therapy, including yoga and progressive muscle relaxation, same frequency and timing.
Appleby 1997 (2)	Intervention: allocation to fluoxetine or placebo, and to one or six sessions of cognitive-behavioural coun selling with a focus on **C**hildcare advice, **R**eassurance, **E**njoyment, **S**upport from others and **T**argets, delivered by psychologists over 3 months.
Cooper 1997 (24, 75)	Interventions: 1 of 3 treatments (nondirective counselling, cognitive-behavioural therapy, dynamic psychotherapy) compared with routine primary care, carried out at home with a weekly visit from 8 to 18 weeks by 1 of 6 therapists, 3 specialists and 2 generalists, each trained in 2 of the treatments, including 2 Health Visitors.
O'Hara 2000 (82)	Intervention: Individual interpersonal therapy (IPT) offered by ten highly trained therapists in 12 weekly 1-hour sessions, using a standard manual with monitoring for adherence to it, or to a waiting list control group, focus on common IPT problem areas, conflict with partner or extended family, loss of work/social roles, losses associated with birth or death of significant others.
Misri 2000 (71)	Six, weekly psychoeducational visits, each including a review of medication, with a follow-up visit 1 month later. In the experimental arm, the woman's partner was invited to the 2nd and 4th visits, and positive practically supportive interactions around childcare and housework were encouraged, compared with the weekly visits without partner involvement.
Chen 2000 (20)	Intervention: postnatal support group of 5 to 6 mothers (and infants) with a registered nurse researcher as group leader; 4 weekly sessions of 1.5 to 2 hours, focus on transitions to motherhood, postnatal stress management, communication skills, and life planning, some flexibility in duration and content.
Chabrol (B) 2002 (18-19)	Intervention: 5 to 8 weekly home visits from therapists integrating supportive, educational, cognitive-behavioural and psychodynamic components, focus on the mother-infant relationship in terms of the mother's personal history.

Table 1. Continued

1st Author, date, reference	Intervention
Honey 2002 (59)	Intervention: psychoeducational group, focus on information about postnatal depression, strategies for coping with difficult child-care situations, eliciting social support, use of cognitive-behavioural techniques to "tackle women's erroneous cognitions on motherhood" and provide strategies for coping with anxiety, use of relaxation.
	Interventions with mother and infant
Heinicke 1999 (50)	Relationship-based weekly home-visit from late pregnancy to 12 months after birth, and a mother-infant group; focus on enhancing the mother's communication and personal adaptation, alternate approaches to her relationship with the child, providing affirmation and support to promote self-efficacy, compared with paediatric follow-up offering development evaluation, feedback on the evaluation and referral to other services as needed.
Horowitz 2001 (60)	Home visits by advanced practice nurses at 4-8 weeks, 10-14 weeks, and 14-18 weeks, videotaped mother-infant interaction (I and C). I group received a coached behavioural intervention at each visit designed to promote maternal-infant responsiveness.
Onaazawa 2001 (83)	Five 1-hour infant massage classes, with a trained instructor encouraging parents to observe and respond to their babies' body language and cues and adjust their touch accordingly, plus a weekly support group including 30 minutes of informal discussions about practical problems and coping strategies vs. the support group meetings only.
Hiscock 2002 (51)	Three fortnightly consultations with a senior paediatric trainee at the maternal and child health centre, development of tailored sleep management plans, education of parents and teaching of "controlled crying" vs. provision of a single sheet describing normal sleep patterns in infants aged 6 to 12 months, without advice on managing sleep problems.

those described among the universal antenatal trials, offered to women with a history of major depressive disorder. This was designed to provide social support, enhance early detection of symptoms, and speed referral and treatment if that became necessary. The final trial in this group had an education and additional support focus, providing information to the women identified as at-risk for postnatal depression, informing her primary care providers about her increased risk, and offering referral within antenatal care to psychiatry or social work (98).

Only one trial of an *indicated antenatal* intervention for women with antenatal depression was found (91). This compared individual interpersonal psychotherapy with individual parenting education.

Interventions in labor, evaluated in four trials, all involved the provision of continuous labor support. In three of them, support was provided by a "doula" or lay female companion, usually from the local community, to be with the woman during labor. One trial was completed in South Africa (80;104) and the other two in the United States (38;57). The fourth compared continuous support from a trained labor support nurse with standard care in a large study of Canadian and U.S. hospitals (55).

Six diverse trials of potentially *universal postnatal* interventions have been reported. Two, carried out during the postnatal stay in hospital, involved postnatal "debriefing" or "listening and discussion" by a midwife (61;85). The other four were changes to the provision of standard posthospital postnatal care. The first changed the timing of the postnatal check from six weeks after birth to a week after hospital discharge (44). The second offered a substantial increase in practical support at home (72;73). The third, using a factorial design, provided an information package, an invitation to a new mothers' group, both interventions or neither (87). The fourth was a complex design (cluster-randomized) and a complex intervention—evidence-based, re-designed postnatal care—compared with the usual care provided by community midwives. It involved randomization of the general practices to which the midwives were attached (67).

Four trials of very different *selective postnatal* interventions were identified. One was a trial of midwifery-led debriefing in hospital offered to women who had experienced an operative birth (90). The second provided a home-visiting support and educational intervention for women with major social risk factors (3;4). The third involved screening women in hospital with the Edinburgh Postnatal Depression Scale (EPDS) to detect those with moderate levels of depressive symptoms and offering them an immediate intervention before hospital discharge with educational, supportive, and cognitive-behavioral components provided by a trained and supervised therapist (18;19). The fourth also screened women with the EPDS after birth. Those with scores >9 were recruited to a trial of telephone-based peer support, provided by trained volunteers who had themselves recovered from an episode of postnatal depression (28).

Eleven trials of *indicated postnatal* interventions for women diagnosed with depression or probable depression were found. Seven were counseling interventions (a range of

Table 2. Mental Health Outcomes of *Universal Antenatal* Interventions to Reduce Postnatal Depression

1st Author, date, reference	Outcome measure (s)	Summary outcomes	
Gordon 1959-65 (40-42)	"Emotionally distressed" on 4-point scale, 6 weeks	13/85 vs. 28/76	RR 0.42 (0.23-0.74)
	"Having problems," 6 months	1/46 vs. 10/36	RR 0.08 (0.01-0.58)
	• Data not adjusted for cluster randomisation, trial excluded		
Shields 1997 (88)	EPDS ≥13, 7 weeks	71/426 vs 84/362	RR 0.72 (0.54- 0.95)
	EPDS, mean score	8.1 (SD 4.9) vs. 9.0 (SD 4.9), $p = 0.01$	
	EPDS median score	8 vs. 8	
Waldenström 1999, 2000 (96-97)	EPDS ≥13, 2 months	51/333 vs. 46/285	RR 0.95 (0.66-1.37)
Biro 1999, 2000 (8-9)	EPDS ≥13, 4 months	58/358 vs. 40/323	RR 1.31 (0.90-1.90)
Hayes 2001 (49)	POMS median score depression, 8–12 weeks	5 vs. 4, $p = 0.37$	
	POMS median score depression, 16–24 weeks	4 vs. 4. $p = 0.99$	

RR, relative risk; SD, standard deviation; EPDS, Edinburgh Postnatal Depression Scale; POMS, Profile of Mood States.

modalities), provided by a trained primary care provider such as a Health Visitor (58); a Child Health Nurse, (101); by a psychologist, therapist, or psychiatrist (2;18;19;71;82); or both (24). The trial of Appleby and colleagues had a complex factorial design involving one or six sessions of cognitive-behavioral counseling and either fluoxetine or placebo, with breastfeeding women excluded (2). The trial of Cooper and colleagues compared three different modalities (nondirective counseling, cognitive-behavioral therapy, and psychodynamic therapy) with routine primary care and also compared their implementation by specialists or generalists with additional training (24;75). In the one trial where the intervention was provided by a psychiatrist, the comparison arm was standard psychiatric follow-up for six weeks with the intervention involving the partner's attendance at the second and fourth visits and a focus on increasing the partner's support (71). Three trials implemented a group intervention (20;36;59). Like the trials described earlier in relation to *selective antenatal* interventions the groups combined educational and supportive components. The final trial by Field and colleagues compared massage therapy with relaxation therapy for disadvantaged and depressed young mothers (35).

Four trials—three in which women were selected as being at increased risk of depression, and one for women currently depressed—focused on mother-infant interaction. The first, which extended over a year, was a weekly home-visiting, relationship-based intervention offered to women characterized by poverty and a lack of support, identified in late pregnancy and having their first child (50). The second identified women two to four weeks after birth with mild to severe depressive symptoms and randomized them to receive a coached behavioral intervention designed to promote maternal-infant responsiveness (60). The third offered a sleep management plan and advice on "controlled crying" from a senior pediatric trainee, to mothers of six- to twelve-month-old babies with severe sleep problems. Women in both the intervention and comparison arms received information about normal sleep (51). The fourth trial compared a support group plus infant massage classes with a support group alone for women identified as depressed four weeks after birth (83).

The mental health outcomes of these trials are given in Tables 2 through 8. Among the *universal antenatal* interventions the trial by Gordon and Gordon (40) appeared to be highly effective and the trial was very influential for the design of subsequent trials. Although its design, with randomization of classes is very appropriate, the analysis is more complex, because the assumption that all the participants are independent no longer holds. In addition, the outcome measure, although well designed and measured, is not sufficiently similar to depression and probable depression for the trial to be included. Hayes' one-to-one intervention was not effective, despite its careful design, thoughtful intervention, and implementation (49). The three team midwifery care trials designed to improve continuity of care and carer all had very similar results with overlapping confidence intervals, with no consistent evidence of a beneficial effect on postnatal depression (8;88;96).

Table 3 provides outcome data on *selective* and *indicated antenatal* interventions. The trial of Elliott and colleagues (31), like the Gordons' trial, has been very influential, and like that trial reported an intervention that was effective. However, the trial was not randomized but had historical controls and, thus, has been excluded. The three group interventions that followed were not effective, two of them reporting problems with participation in the program (14;15;92;93). The fourth had promising results, although the trial was very small, with only thirty-five participants in total (105). The enhanced continuity of care trial had no effect on depressive illness either in pregnancy or after birth: 23 percent of women in both arms were depressed in the first three months after birth (65). Webster's intervention, which combined careful screening during antenatal care with a low-key, low-cost intervention, was not shown to be effective (98). The only trial of an intervention to reduce current major *antenatal depression* (91), was effective in reducing the severity of depression and improving depressive symptoms, measured with the Clinical Global Impression. Drop-outs and low levels of participation were high in this study where the women, many of them immigrants, lived in highly adverse social circumstances.

Table 3. Mental Health Outcomes of *Selective Antenatal* Interventions and *Indicated Antenatal* Interventions to Reduce Postnatal Depression

1st Author, date, reference	Outcome measure (s)	Summary outcomes	
Elliott 1988, 2000 (31-32, 63)	EPDS median score	3 vs. 8	
	Present State Exam. "case" or borderline, first 3 months	9/47 vs 19/51	RR 0.51 (0.26-1.02)
	• Historical controls, not randomised, excluded		
Stamp[a] 1995 (92-93)	EPDS ≥13, 6 weeks	8/64 vs. 11/64	RR 0.73 (0.31-1.69)
	EPDS ≥13, 12 weeks	7/63 vs. 10/65	RR 0.72 (0.29-1.78)
	EPDS ≥13 6 months	9/60 vs. 6.61	RR 1.52 (0.58-4.02)
Buist[a] 1998 (16)	Beck Depression Inventory,		
	mean score, 6 weeks	7.40 vs. 9.06	
	mean score, 6 months	7.57 vs. 8.09	
	EPDS ≥13, 6 weeks	0/20 vs. 0/16	(RR 0.81 (0.02-42.8)
	EPDS ≥13, 6 months	0/14 vs. 0/11	(RR, OR not calculable)
Brugha[a] 2000 (14-15; 99-100)	General Health Questionnaire—	24/94 vs. 21/96	RR 1.17 (0.70-1.95)
	Depression subscale = 2		adjusted OR 1.19 (0.59-2.37)
	EPDS ≥11	15/94 vs. 18/96	RR 0.85 (0.46-1.59)
			adjusted OR 0.83 (0.39-1.79)
	Schedule for Clinical Assessment in Neuropsychiatry (ICD-10) F32/33	3/94 vs. 6/96	RR 0.51 (0.13-1.98)
			adjusted OR 0.47 (0.12-1.99)
Zlotnick[a] 2000 (105)	Beck Depression Inventory, mean score, 6 weeks	8.4 (SD 7.8) vs. 11.3 (SD 4.8)	
	No substantial fall in BDI	11/17 vs. 16/18	RR 0.73 (0.49-1.07)
	SCID Depression	0/17 vs. 6/18	RR 0.08 (0.00-1.34)
Webster 2003 (98)	EPDS ≥13, 4 months	46/192 vs. 50/177	RR 0.85 (0.60-1.20)
Marks 2002 (65)	SCID (any postnatal illness)	10/43 vs. 10/44	RR 0.96 (0.41-2.23)
	EPDS mean score, 4 weeks	10.1 (SD 5.9) vs. 8.6 (SD 4.2)	
	EPDS mean score, 3 months	7.5 (6.5) vs. 7.5 (SD 5.3)	
	Indicated antenatal		
Spinelli 2003 (91)	Postpartum depression (clinical diagnosis)	1/8 vs. 2/3	RR 0.19 (0.03-1.39)

EPDS, Edinburgh Postnatal Depression Scale; RR, relative risk; OR, odds ratio; ICD, International Classification of Diseases.
[a] Data not adjusted for within-group effects.

The mental health benefits of doula care *in labor*, found at short-term follow-up in one South African trial (104), were not sustained some weeks later (80) and have not been replicated either in the other doula trials or in a large trial of continuous labor support by a trained labor support nurse (38;55;57; Table 4).

The *universal postnatal* interventions summarized in Table 5 include two debriefing interventions. The very large trial of Priest and colleagues virtually ruled out any substantial effect of this intervention on depression in the first year after birth (85). The trial of Lavender and Walkinshaw (61) assessed outcomes very soon after birth (three weeks) and also found extremely high levels of anxiety and depression in the standard care arm, both of which make it unlikely that the very large reported benefit can be expected elsewhere; this trial is a true outlier. The other universal trials had

Table 4. Mental Health Outcomes of *Continuous Support* (Doula or Trained Labor Support Nurse) *in Labor*

1st Author, date, reference	Outcome measure(s)	Summary outcomes	
Hoffman 1992 (57)	Instrument not described, 8-10 weeks after birth	No significant independent effect on postpartum psychological adaptation of doula support, no further details	
Wolman 1993 (104)	Pitt Depression Inventory mean score (standard error), 6 weeks	10.4 (0.77) vs. 23.3 (1.28)	
	Pitt Depression Inventory high score, ≥35, 6 weeks	0/74 vs. 16/75	
Nikodem 1998 (80)	EPDS ≥13, 4 months	18/48 vs. 16/42	RR 0.98 (0.58-1.67)
Gordon 1999 (38)	Short Form 36, Mental Health Index, telephone interview at 4 to 6 weeks	No differences between doula care and usual care on mean scores, no further details.	
Hodnett 2002 (55)	EPDS ≥13, 6 to 8 weeks	245/2836 vs. 277/2765	RR 0.86 (0.73-1.02)

EPDS, Edinburgh Postnatal Depression Scale; RR, relative risk.

Table 5. Mental Health Outcomes of *Universal Postnatal* Interventions

1st Author, date, reference	Outcome measure (s)	Summary outcomes
Gunn 1998 (44)	EPDS, mean score, 3 months	7.38 (SD 5.31) vs. 7.48 (SD 5.35), $p = 0.85$
	EPDS, mean score, 6 months	5.87 (SD 5.37) vs. 6.08 (SD 5.14), $p = 0.67$
	EPDS $\geq$13, 3 months	39/232 vs. 33/243 RR 1.24 (0.81-1.90)
	EPDS $\geq$13, 6 months	27/232 vs. 31/243 RR 0.91 (0.56-1.48)
	SF-36 mental health domain mean score 3 months	70.3 (SD 19.7) vs. 72.1 (SD 18.1), $p = 0.28$
Lavender 1998 (61)	Hospital Anxiety and Depression Scale	
	Depression $\geq$11	5/58 vs. 31/56 RR 0.16 (0.07-0.37)
Priest 2003 (85)	DSM-IV Criteria for depression in the year after birth	156/875 vs. 158/870 RR 0.98 (0.80-1.20)
Morrell 2000 (72-73)	EPDS, mean score, 6 weeks	7.4 (SD 5.2) vs. 6.7 (SD 5.5) $p = 0.05$
	EPDS, mean score, 6 months	6.6 (SD 5.1) vs. 6.7 (SD 5.6)
	EPDS $\geq$12, 6 weeks	49/276 vs. 48/266 RR = 0.98 (0.69-1.41)
	EPDS mean change, 6 weeks to 6 months	0.6 (SD 4.9) vs. −0.2 (SD.3), $p = 0.35$
	SF-36 mental health, mean score, 6 weeks	72.0 (SD 17.5) vs. 72.7 (SD 17.8) $p = 0.60$
	mean score, 6 months	72.8 (SD 17.3) vs. 74.0 (SD 17.5) $p = 0.30$
Reid 2002 (87)	EPDS, mean score 3 months	5.6 (SD 4.87), 6.1 (SD 4.9), and 6.1 (SD 5.34) vs.
	EPDS, mean score 6 months	5.9 (SD 4.35)
	EPDS $\geq$12, 3 months	5.7 (SD 4.29), 5.4 (SD 5.29) and 5.3 (SD 5.74) vs.
	EPDS $\geq$12, 6 months	5.0 (SD 4.44)
Pack/no Pack	EPDS $\geq$12, 3 months	78/535 vs. 23/197 RR = 1.35 (0.81-1.93)
Group/no Group	EPDS $\geq$12, 3 months	77/521 vs. 18/188 RR = 1.54 (0.95-2.51)
Pack/no Pack	EPDS $\geq$12, 6 months	48/356 vs. 53/376 RR = 0.96 (0.67-1.37)
Group/no Group	EPDS $\geq$12, 6 months	55/344 vs. 46/388 RR = 1.35 (0.94-1.94)
		50/345 vs. 45/364 RR = 1.17 (0.81-1.71)
		49/339 vs. 46/370 RR = 1.16 (0.80-1.69)
MacArthur 2002 (67)	EPDS, mean of cluster means, difference (95% CI),	6.40 vs. 8.06, −1.66 (−2.49 to −0.83), $p < 0.0001$
	Multilevel modelling, OR (95% CI)	OR −1.92 (−2.55 to −1.29)
	EPDS $\geq$13, difference (95% CI)	14.39% vs. 21.25%, −6.85 (−11.9 to −1.71), $p < 0.01$
	Multilevel modelling, OR (95% CI)	OR 0.57 (0.43 to 0.76)

EPDS, Edinburgh Postnatal Depression Scale; RR, relative risk; SD, standard deviation; OR, odds ratio; CI, confidence interval; DSM, Diagnostic and Statistical Manual.

several points in common: all were interested in physical health as well as mental health outcomes, all used the SF-36 and the EPDS as standard outcome measures, and all measured outcomes at several time points after birth. The striking finding is that three of the four trials had no effects on mental or physical health (44;72;87), but the fourth demonstrated a large mental health benefit in terms of mean EPDS and SF-36 mental health scores and probable depression (67). MacArthur and colleagues developed a very careful and relatively intensive intervention, embedded in existing community-based midwifery postnatal services.

The *four selective postnatal* interventions (Table 6) are quite diverse. Another large debriefing trial, by Small and colleagues, restricted to women who experienced an operative or assisted delivery, was unable to detect any benefit of the intervention (90); the same finding as that of Priest

Table 6. Mental Health Outcomes of *Selective Postnatal* Interventions

1st Author, date, reference	Outcome measure (s)	Summary outcomes
Armstrong 1999, 2000 (3-4)	EPDS, mean score, 6 weeks	5.67 (SD 4.14) vs. 7.90 (SD 5.89), $p = 0.004$
	EPDS, mean score, 17 weeks	5.75 (SD 5.51) vs. 6.64 (SD 5.88)
	EPDS $\geq$13, 6 weeks	5/86 vs. 18/88 RR 0.28 (0.11-0.73)
	EPDS $\geq$13, 17 weeks	13/80 vs. 18/80 RR 0.72 (0.38-1.37)
Small 2000 (90)	EPDS, mean score, 6 months	7.16 (SD 5.68) vs. 6.72 (SD 5.50)
	median (range)	6 (0-28) vs. 6 (0-29)
	EPDS$\geq$13, 6 months	81/467 vs. 64/450 RR 1.22 (0.90-1.65)
	SF-36 Mental health subscale, mean score, 6 months	69.69 (SD 18.79) vs. 71.20 (SD 18.14), $p > 0.3$
Chabrol (A) 2002 (18-19)	EPDS $\geq$11, 4 to 6 weeks	29/97 vs. 55/114 RR 0.62 (0.43-0.89)
Dennis 2003 (28)	EPDS >12, 3 months	2/20 vs. 9/22 RR 0.24 (0.06-1.00)
	EPDS >12, 4 months	3/20 vs. 11/21 RR 0.29 (0.09-0.88)

EPDS, Edinburgh Postnatal Depression Scale; RR, relative risk; SD, standard deviation; SF-36, Short Form 36.

Table 7. Mental Health Outcomes of *Indicated Postnatal* Interventions

1st Author, date, reference	Outcome measure (s)	Summary outcomes
Holden 1989 (58)	Research Diagnostic Criteria for depression	8/26 vs. 15/24 RR = 0.49 (0.26-0.95)
Fleming 1992 (36)[a]	Current Experience Scale	No intervention effect, nor mood by intervention interaction, for any comparisons [no details]
Wickberg 1996 (101)	DSM-III-R depression	3/15 vs. 12/16 RR = 0.27 (0.09-0.76)
Field 1996 (35)	POMS mean score, depression day 10 preintervention and postintervention	20.39 to 9.06 (M) $p = 0.005$ vs. 18.56 to 17.12 (R) $p > 0.05$, No intervention effect over time in either arm
Appleby 1997 (2)	Revised Clinical Interview Schedule, geometric mean score, 12 weeks	8.0 (F + 1C) vs. 7.0 (F + 6C) vs. 17.5 (P + 1C) vs. 9.9 (P + 6C)
	EPDS geometric mean score, 12 weeks	5.4 vs. 5.3 vs. 9.8 vs. 9.9
Cooper 1997 (24; 75)	DSM-III-R criteria for major depressive disorder (Structured Clinical Interview)	20/42 (C) 17/41 (CBT), 10/40 (DP) vs. 29/48 (RPC)
		Pooled 47/123 vs. 29/48 RR = 0.63 (0.46-0.87)
O'Hara 2000 (82)	Hamilton Rating Scale for Depression< 7	18/48 vs. 44/5 RR 0.43 (0.30-0.64)
	Beck Depression Inventory <10	21/48 vs. 44/51 RR 0.51 (0.36-0.71)
Misri 2000 (71)	MINI depression: visit 7	3/16 vs. 8/13 RR 0.30 (0.10-0.92)
	EPDS mean score, visit 7	8.6 (5.2) vs. 14.7 (7.2)
Chen 2000 (20)[a]	Beck Depression Inventory< 10	10/30 vs. 18/30 RR 0.56 (0.31-1.00)
Chabrol (B) 2002 (18-19)	Clinical diagnosis of major depression at 10–12 weeks	2/21 vs. 26/38 RR 0.14 (0.04-0.53)
	Hamilton Depression Rating Scale, mean score, 10–12 wks	5.4 (3.5) vs. 15.8 (4.6), $p < 0.0001$
	Beck Depression Inventory, mean score, 10-13 weeks	4.0 (2.9) vs. 15.3 (4.7), $p < 0.0001$
	EPDS mean score, 10-12 weeks	5.8 (2.6) vs. 13.5 (3.7), $p < 0.0001$
Honey 2002 (59)[a]	EPDS mean score, recruitment	19.35 (4.4) vs. 17.95 (4.0)
	EPDS mean score, post intervention	14.87 (6.0) vs. 16.95 (5.4)
	EPDS mean score, 6 months later	12.55 (4.6) vs. 15.63 (7.3)
	EPDS >12, post intervention	8/23 vs. 14/22 RR 0.29 (0.29-1.04)
	EPDS >12, 6 months later	7/20 vs. 13/19 RR 0.26 (0.26-1.00)

EPDS, Edinburgh Postnatal Depression Scale; RR, relative risk; DSM, Diagnostic and Statistical Manual; POMS, Profile of Mood States.
[a] Data not adjusted for within-group effects.

and colleagues above. Armstrong and colleagues' intensive home-visiting intervention provided to women as at-risk on social grounds had a large effect in the short term that was not sustained through to four months (3;4). In contrast, the postscreening psychological intervention of Chabrol and colleagues during the postnatal hospital stay was associated with a large reduction in the proportion of women having moderate to severe depressive symptoms four to six weeks later (18;19). Similarly, the telephone-based peer support provided to women after screening in Canada was effective in reducing probable depression (28).

The outcomes of *indicated postnatal* interventions summarized in Table 7 demonstrate a consistent and substantial reduction in depression/probable depression after the six counseling interventions, regardless of the model of therapy or the professional background of the therapist (18;19;24;58;71;82;101). Cooper and colleagues, in a recent more detailed report of their trial, show that while all three treatments had a significant impact on maternal depressive symptoms at 4.5 months, only psychodynamic therapy reduced clinically diagnosed depression (24). By nine months after birth, spontaneous recovery among those receiving routine primary care meant that women who had received the therapies no longer differed from those in primary care. These authors also point out that, despite the high acceptability of the treatments offered, a minority of women were reluctant to accept home visiting and they suggest that these women are likely to be particularly at-risk of adverse outcomes (75). The trial of Appleby and colleagues, which combined fluoxetine or placebo with one or six counseling sessions, reported highly significant improvement in all four groups, with a greater improvement in those receiving fluoxetine than placebo (2). The three group interventions had rather different interventions and different outcomes, with the latter two identifying a probable benefit of participation on depression (20;36). The trial comparing massage therapy with relaxation therapy found the former to be more effective on each occasion, but there were no effects sustained over time (35).

Table 8 summarizes the impact of four different interventions focused on mother-infant interaction. Those with a focus on mother-infant interaction itself had no effect on depression (50;60). Baby massage classes and a support group were reported to have a beneficial effect on one measure, but as with other group trials, there was no adjustment for within-group effects (83). The trial of Hiscock and colleagues that aimed to improve infant sleep patterns did not have a significant effect on the proportion of women depressed at two or four months, but the stratified analysis demonstrated a

Table 8. Mental Health Outcomes of Interventions with *Mother and Baby*

1st Author, date, reference	Outcome measure (s)	Summary outcomes
Heinicke 1999 (50)	Beck Depression Inventory & Spielberger Anxiety Inventory, converted into mean factor score (SD)	
	Before birth	0.05 (0.99) vs. 0.08 (0.85)
	1 month	0.04 (1.09) vs. −0.12 (0.92)
	6 months	−0.01 (1.02) vs. −0.81 (1.10)
	12 months	0.23 (1.07) vs. −0.15 (1.00)
		The average depression/anxiety factor score increased for the home-visited group and decreased for the paediatric follow-up group, but neither the trends nor the group differences are statistically significant.
Horowitz 2001 (60)	Beck Depression Inventory, mean scores (SD)	
	4-8 weeks	15.5 (SD 1.2) vs. 13.2 (SD 0.9)
	10-14 weeks	11.0 (SD 1.0) vs. 10.1 (SD 0.8)
	14-18 weeks	10.3 (SD 1.0) vs. 9.5 (SD 0.8)
Onazawa 2001[a] (83)	EPDS median score, 14 weeks	5 vs. 6
	Change in median score from 6 to 14 weeks	−12 vs. −6, $p = 0.03$
Hiscock 2002 (51)	EPDS ≥13, 2 months	6/76 vs. 6/76 RR 1.00 (0.34-2.97)
[and unpublished data]	EPDS ≥13, 4 months	5/75 vs. 8/71 RR 0.62 (0.21-1.81)
	EPDS score 10–12 at baseline, median score	
	EPDS median score 2 months	11 vs. 11
	EPDS median score 4 months	4.5 vs. 7
	EPDS >12 at baseline, median score	4.5 vs. 6.5
	EPDS median score 2 months	14 vs. 15
	EPDS median score 4 months	7 vs. 11
		7.5 vs. 11

EPDS, Edinburgh Postnatal Depression Scale; RR, relative risk; SD, standard deviation.
[a] Data not adjusted for within-group effects.

marked reduction in depressive symptoms associated with the intervention (51).

Fixed and random effects meta-analysis comparing interventions grouped by their timing and the nature of the intervention are shown in Table 9. Trials were excluded if they did not include a measure of depression or probable depression (2;35;49;50;60;83), if there were only summary statements on the outcomes (36;38;57), or the intervention was with the women's partner (71). Trials were included in the meta-analyses if the mental health outcome was depression or probable depression, if the intervention was compared with standard care or routine primary care, or if the comparison group received an intervention perceived as a placebo. Examples in the latter category were individual parent education (91), a leaflet about practical sources of help after operative birth (90), being put on a waiting-list (82), or an information sheet on normal sleep patterns (51).

The pooled data show that only the indicated postnatal interventions had a substantial impact on reducing postnatal depression and that there was no significant heterogeneity across the trials in this category. The one reservation to be made in relation to this inference is that graphical representation [not shown] of these trials in terms of study power suggests that there may be some publication bias with "missing" small negative trials. Both individual and group interventions were effective.

The marked heterogeneity in the universal postnatal trials reflects the individual trial outcomes (Table 5). Four large trials of different supportive interventions (44;72;85;87) were able to exclude any worthwhile effect, while another large trial (67) of a different and complex intervention was highly effective. (One small trial with several measurement problems also reported a very large effect [61]). Similarly, the selective postnatal interventions, where there was significant heterogeneity, included two small trials with promising results (19;28), one large trial showing no impact on depression (90), and another whose promising early effects were not sustained (3;4). It is also possible to calculate from the risk difference across the trials the number of women needing to be given an effective intervention (the number needed to treat, (NNT) for one "case" of depression or probable depression to be prevented or treated (1). For individual postnatal counseling in women diagnosed as depressed, NNT = 3, with a 95 percent CI of 2 to 4. The NNT for women receiving redesigned postnatal care is fourteen, with a 95 percent CI of 9 to 33.

DISCUSSION

Methodologic Issues

Participation. The proportion of women accepting an invitation to participate in a trial will be affected by their

Table 9. Fixed and Random Effects Meta-Analysis Comparing Interventions vs. Standard Care for Depression/"Probable Depression"

Classification and timing of intervention	No of trials	Effects model	RR (95% CI)	*p* value for heterogeneity
Universal antenatal	3	Fixed	0.91 (0.75-1.10)	0.04
		Random	0.95 (0.64-1.40)	
Selective antenatal	6	Fixed	0.82 (0.64-1.06)	0.93
		Random	0.82 (0.64-1.06)	
In labor	2	Fixed	0.87 (0.75-1.02)	0.64
		Random	0.87 (0.75-1.02)	
Universal postnatal	6	Fixed	0.85 (0.75-0.97)	<0.0001
		Random	0.84 (0.59-1.20)	
Selective postnatal	4	Fixed	0.86 (0.70-1.07)	0.006
		Random	0.71 (0.41-1.24)	
Indicated postnatal	7	Fixed	0.53 (0.44-0.64)	0.20
		Random	0.51 (0.40-0.65)	
Specific interventions				
Continuity of care (universal + selective)	4	Fixed	0.92 (0.76-1.10)	0.09
		Random	0.94 (0.70-1.27)	
"Debriefing" (universal + selective)	3	Fixed	0.89 (0.75-1.05)	0.001
		Random	0.67 (0.35-1.29)	
Postnatal counselling (indicated)	5	Fixed	0.52 (0.42-0.65)	0.068
		Random	0.46 (0.32-0.67)	

RR, relative risk; CI, confidence interval.

attitude to trials in general as well as by the nature of the intervention. Low participation at recruitment is compatible with otherwise excellent trial quality, but it may be a marker that this intervention will not be widely acceptable within routine health services, something that has implications for the transfer of an effective intervention strategy into policy and practice. One example from the antenatal trials with women likely to develop postnatal depression is that 47 percent of women refused participation in the group program "Survival Skills for Moms" (105), and one from the postnatal trials is that almost two-thirds of eligible women refused to take part in a trial of additional practical home support after birth (72;73). Evidence from the trial of Appleby and colleagues suggests that the use of medication may be perceived as particularly problematic by women after birth, even those who are not breastfeeding (2).

Blinding (Masking). There is no possibility in trials with complex interventions such as counseling, home support, or debriefing that the nature of the intervention can be concealed from the participants. This finding raises the possibility that responses to allocation, particularly disappointment, might contribute to differences between the two arms of the trials. One example is continuity of care trials where the proportion who responded to the follow-up, was substantially higher in the intervention than the standard care arms (8;88;96). Contributing factors to this response difference, other than disappointment, may have been closer relationships between women and the midwife team, especially in the Scottish trial where continuity of team care extended into the postnatal period both in hospital and at home (88).

Screening. The utility of interventions designed for women at increased risk of depression depends in part on the screening properties of the instrument used to define the selected group. Unfortunately, the sixteen screening tools developed for use antenatally (publications to March 2002), do not have adequate sensitivity, specificity, positive and negative predictive values or likelihood ratios for their use to be recommended (5).

Sample Size. The classification of interventions as universal, selective, and indicated has implications for a study's sample size. A strategy that is to be applied to the whole population of pregnant women (a *universal* strategy) needs to be designed to reduce the expected prevalence of depression from around 15 percent or 18 percent in those receiving standard care. A strategy to be applied to women at increased risk of depression (a *selective* strategy) needs to be designed to reduce an expected prevalence of depression from around 30 percent or 40 percent in those receiving standard care. A strategy to be applied to women in whom depression or probable depression has been identified (an *indicated* group) needs to be designed to reduce the expected prevalence of depression from around 50 percent in those receiving standard care. A 20–25 percent relative risk reduction in a major outcome would be regarded as an important effect in most clinical contexts; one that the investigator would not like to miss. A large proportion of the completed trials, in all categories, were too small to detect or rule out realistic and clinically important effects.

Deciding on the clinically important difference is not a statistical issue but a decision that needs to be made by the

clinical investigator, who is the person best placed to define the size of a clinically and practically worthwhile outcome. Unfortunately, it is relatively common for investigators to design a trial with the hypothesized effect size being taken from an earlier trial instead. Among the five trials of antenatal strategies for women screened as at-risk, only two (14;93) included a sample size justification. In both cases, the research group attempted to replicate the very large effects described in early publications by Elliott and colleagues (31), and Gordon and Gordon (40), which was a relative risk reduction of the order of 57 to 60 percent. The former used historical controls, the latter did not adjust for clustering, so that, in both cases, the apparent large effects were misleading.

Clustering in Group Interventions. When whole groups rather than individuals are randomized the analysis needs to take into account the probability that the groups (antenatal classes, patients from different GP practices or from different hospital wards) differ from one another to begin with. Within a group such as an antenatal class, the group members are likely to be more similar to one another than a random sample of pregnant women: there will be some degree of intragroup correlation with increased homogeneity. At the same time, there will be greater differences between groups than if groups were random samples of the population (increased heterogeneity between groups). These predictable effects increase the variance within the study and need to be built into estimation of the required sample size (30;76). The effects also need to be adjusted for in the analysis, as they were in the trial of MacArthur and colleagues (67).

When women are randomized to an intervention involving small group participation, there is no guarantee that the groups are similar to begin with. The subsequent interactions between group members, and their interaction with the group facilitator/leader, is likely to increase within-group differences. In fact, such within-group effects are potentially an important aspect of the intervention. Whether these effects are negative or positive, their impact on the study outcomes is likely to be to increase the homogeneity within each group and to increase the heterogeneity between groups. This change requires an adjustment in the analysis of health outcomes, an adjustment which usually increases the confidence interval for any point estimate. None of the trials included in this review that involved an intervention involving participation in a group activity carried out adjustments.

Attrition. Attrition in this study is used to define the extent to which women recruited to the trial dropped out in the course of the intervention phase. It may be a useful marker of the acceptability of an intervention. One example was the trial of fluoxetine, placebo, and/or one or six counseling sessions (factorial design). There was a low initial participation rate (46 percent), because women were reluctant to accept the chance of being allocated to taking medication, and 30 percent of those who agreed to participate subsequently withdrew, a large proportion because of medication (2). When an intervention involved a large number of extra classes, women having a second or later baby had a much lower participation than women having a first child (31), but one trial restricted to primiparous women also had poor attendance (14). The trial of interpersonal psychotherapy to reduce antenatal depression defined participation in the intervention as attending one or more program session, although the intervention had been designed to extend over sixteen weeks (91). Despite this minimal participation, twelve of fifty (24 percent) of those recruited did not qualify.

Loss to Follow-Up. Loss to follow-up reduces the effective sample size of a planned study, as does attrition. A relatively small number of the trials in this review, which included a rationale for the sample size also factored in likely loss to follow-up (3;44;72), and several others estimated that their recruitment provided them with some excess capacity (e.g., 67;85). Inadequate funding to carry out intensive follow-up, major social disadvantage, poor mental or physical health among participants, and services that are not free at the point of delivery, can all adversely affect follow-up.

Differential loss to follow-up in the two arms of a trial is a concern, as it may mask or exaggerate a true difference in the health outcomes. A clear example in this review is the trials of enhanced continuity of care where outcomes were assessed by postal questionnaire. In all three universal trials, women in the new model of care were more likely to return the follow-up questionnaire: 69 percent versus 42 percent, 79 percent versus 70 percent, and 77 percent versus 67 percent (8;88;96). Even a small interaction between depressive symptoms and dissatisfaction with the allocated model of care, might tip the balance in the reported outcomes.

Postnatal Counseling Interventions. The only trial that compared specialist counselors with primary care practitioners given additional training, that of Cooper and colleagues, reported that the outcome of those who received nondirective counseling or cognitive-behavioral therapy from specialists was unexpectedly poor, compared with those receiving the same interventions from Health Visitors. They attribute the difference to the fact that health visitors are experienced in home visiting, and their interventions were implemented at home (24;75).

CONCLUSIONS

Implications for Practice

There is strong evidence that postnatal counseling interventions (all modalities tested), provided to women with depression or probable depression, by professionals from a variety of backgrounds after specific additional training, will reduce depressive symptoms and depression substantially, with an NNT of two to three (1).

Universal and selective antenatal interventions and universal postnatal interventions have not been shown to be effective with the important exception of the complex

intervention "redesigned community postnatal care" embedded in the UK system of community midwifery (68), which had an NNT of fourteen, range nine to thirty-three.

Within maternity care, neither continuity of care, doula support in labor, nurse support in labor, nor postnatal debriefing by a midwife can be recommended as strategies for reducing postnatal depression. Interventions to enhance mother-infant interaction cannot be recommended to reduce maternal depression.

Implications for Research

Collaboration between those involved in mental illness care/mental health promotion, and those involved in the design, implementation, and analysis of trials is a high priority. Future trials need to be designed with adequate power to detect clinically important effects in relation to the intervention classification (universal, selective, indicated), and with sample sizes adjusted to take into account probable attrition and loss to follow-up. There is a need to address within-group effects in the design and analysis of group interventions.

Despite the widespread interest and concern about the implications of maternal depression for child development, very few trials have measured child health and development outcomes. New trials need to take this on board.

McLennan and Offord suggest criteria for evaluating whether postpartum depression is an appropriate target to reduce poor child outcomes (69). This work needs to be taken into account in determining which proposed targets and associated programs have the right characteristics to be considered for large-scale trials.

The development of interventions that can be integrated into existing maternity and community services is a priority, as is planned economic evaluation of new trials. The effectiveness of one intervention that involved attention to physical health problems as well as to mental health (68) suggests the need for inclusion of physical health issues in more new trials.

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