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Prevention and treatment of post-partum depression: a controlled randomized study on women at risk

H. CHABROL,[1] F. TEISSEDRE, M. SAINT-JEAN, N. TEISSEYRE, B. ROGÉ AND E. MULLET

From the Centre d'Etudes et de Recherche en Psychopathologie, Université de Toulouse-Le-Mirail, Toulouse, France

ABSTRACT

Background. Research is needed to evaluate the efficacy of prevention and treatment for post-partum depression.

Method. Subjects were screened with the Edinburgh Post-natal Depression Scale (EPDS) at the obstetric clinic. Mothers at risk ($N = 258$) (EPDS scores $\geqslant 9$) were randomly assigned to a prevention/treatment group or a control group. The prevention group received one cognitive-behavioural prevention session during hospitalization. At 4 to 6 weeks post-partum, subjects were screened again with the EPDS, after drop-out rates (refusals plus no return of the second EPDS) of 25·4% (33/130) in the intervention group and 10·9% (14/128) in the control group. Mothers with probable depression (EPDS scores $\geqslant 11$) were assessed using the Hamilton Depression Rating Scale (HDRS) and the Beck Depression Inventory (BDI). Mothers with major depression continued in the treatment group ($N = 18$) or in the control group ($N = 30$). Treated subjects received a cognitive-behavioural programme of between five and eight weekly home-visits.

Results. Compared with the control group, women in the prevention group had significant reductions in the frequency of probable depression (30·2% *v.* 48·2%). Recovery rates based on HDRS scores of < 7 and BDI scores of < 4 were also significantly greater in the treated group than in the control group.

Conclusions. The study suggests that this programme for prevention and treatment of post-partum depression is reasonably well-accepted and efficacious.

INTRODUCTION

Major depression with post-partum onset is a prevalent condition with frequent negative effects on the mother–infant relationship and children's social–emotional development (Weinberg & Tronick, 1998). Research on childbearing women in the community have shown that about half of those with major depression remain undetected and among those detected, nearly 30% fail to keep clinic appointments (Appleby *et al*. 1988). These findings indicate the need for effective, well-accepted and easily distributed means of prevention and treatment. Although controlled studies are lacking, some studies have suggested the efficacy of antidepressants in the prevention and treatment of post-partum depression (Wisner & Wheeler, 1994; Nonacs & Cohen, 1998). However, although growing data on the safety of antidepressants during lactation exist, the long-term effects of antidepressant exposure through breast-feeding on the infant's developing brain are unknown and their prescription to breast-feeding women requires a case-specific risk–benefit decision assessment (Wisner *et al*. 1996; Stowe *et al*. 2000). Moreover, given that most new mothers prefer to avoid medication, particularly if breast-feeding, it is important that psychosocial interventions be evaluated for prevention and treatment of post-partum depression (Appleby *et al*. 1997; O'Hara *et al*. 2000).

Effective means of identification of women at greater risk for post-natal depression are now

[1] Address for correspondence: Dr Henri Chabrol, 21 rue des Cèdres, 31400 Toulouse, France.

available (Cox *et al*. 1987; Hannah *et al*. 1992). Studies of preventive intervention for post-partum depression are rare (Nonacs & Cohen, 1998) and are often limited by either small samples, lack of control groups, or the use of 'non-standard' therapies. There is only one large randomized controlled study, which recruited 181 women at-risk (Armstrong *et al*. 1999), but it implemented a programme of six home-visits, which was as time-consuming as two of the few controlled studies of psychotherapy for post-partum depression, which also used six sessions (Wickberg & Hwang, 1996; Appleby *et al*. 1997). Although most of studies have some design limitations (O'Hara *et al*. 2000; Boath & Henshaw, 2001), there is growing evidence of the efficacy of psychotherapy for post-partum depression. Holden *et al*. (1989) found that eight weekly sessions of non-directive counselling by health visitors brought about a significantly superior rate of recovery of depressed mothers compared with those of the control group. The comparison of three brief psychological treatments (non-directive counselling, cognitive behaviour therapy directed at infant-management problems, and dynamic psychotherapy centred on the mother–infant relationship) showed that they significantly and equivalently speed up recovery from depression (Cooper & Murray, 1997). The only comparative study with antidepressants has suggested that short-term cognitive-behavioural therapy was as effective as fluoxetine (Appleby *et al*. 1997). Recently, the largest and best-designed psychotherapy study involving 120 subjects in a randomized, controlled trial has suggested that interpersonal psychotherapy is an efficacious treatment for post-partum depression (O'Hara *et al*. 2000). However, more than half of the eligible women declined participation and 20% withdrew from treatment. The relatively high rates of psychosocial treatment refusal and of dropouts in most studies may question the acceptability and applicability of the therapeutic programmes implemented in previous studies. If effective means of detection, prevention and treatment have been designed, it remains to continue evaluative studies, particularly in order to compare the different psychosocial interventions in terms of efficacy, acceptability and applicability, with one of the main challenges being to reduce the rate of therapeutic non-compliance. This study reports the results of a structured programme of detection and prevention of women at risk, complemented, when necessary, with a structured home-based intervention for post-partum depression.

METHOD

Women successively admitted to three obstetric clinics in Toulouse and Narbonne, France, between December 1999 and March 2000 were screened for the study. Being fully covered under the social healthcare system, these clinics were not discriminatory on the basis of income and admitted patients from diverse socio-economic backgrounds. Of these, 859 subjects were eligible, exclusion criteria being: current treatment with a psychiatrist or a psychologist, or poor French language skills. All subjects were Caucasian. They completed a brief self-report scale, the Edinburgh Post-natal Depression Scale (EPDS) (Cox *et al*. 1987) during their stay at the clinic. The EPDS is a 10-item questionnaire designed to screen for post-partum depression, it has strong validity and reliability in large community surveys (Nonacs & Cohen, 1998) and has been translated and validated in French (Guedeney & Fermanian, 1998). A highly significant positive correlation has been noted between EPDS scores at 5 days and 6 weeks post-partum, a threshold of 10 being predictive of post-partum depression (Hannah *et al*. 1992). A threshold of 9 was selected in this study to improve the chances of identifying women at risk in the early puerperium.

Randomization was implemented through numbered questionnaires. Women scoring $\geqslant 9$ on the EPDS were asked to participate in the prevention group if the questionnaire number was even and in the control group if it was odd. Written informed consent was obtained from all participants. The intervention group received a 1 h prevention session between the second and the fifth day post-partum during their stay at the obstetric clinic. Most subjects stay no more than 3 days at the clinic, with the exception of subjects having had a Caesarean section.

For 75·8% of participants the EPDS and the session took place on the second or third day post-partum. This prevention session comprised three main components: (1) an educational

component imparting information about the realities of parenthood and providing guidance for normal infant development problems; (2) a supportive component featuring empathic listening, encouragement to express negative feelings, and acknowledgement of maternal ambivalence, with an attempt to alleviate guilt by normalizing the mother's experiences; (3) a cognitive-behavioural component, particularly to weaken the oppressive 'shoulds' linked to being a 'perfect mother', and to develop problem-solving. A structured guide with different modules composed of questions and information on different areas was elaborated (baby blues and post-partum depression, the experience of delivery, past events interfering with maternity, normal infant problems such as crying and sleep behaviour, relationships with the subject's own mother and mother-in-law, social support, the required social, familial and conjugal role adjustments, occupational and recreational adjustments, concerns about body shape and sexuality). The development of the session was adapted to the subject's personal circumstance, experiences and knowledge to focus on the most pertinent and useful issues. Prevention sessions were conducted in privacy. Sessions were audiotaped if the subject agreed. Therapists, including five female Master's Degree level students in psychology participated in clinical training and in weekly supervision from the first author based on the audiotapes. Therapist adherence to the treatment guide was monitored through supervision.

Subjects for both the control and the prevention groups were given a second EPDS and a stamped self-addressed envelope with written instructions to complete the questionnaire during the period 4 to 6 weeks post-partum and to return it for analysis. As the French validation study of the EPDS found that the best cut-off was 11, subjects who had an EPDS score of $\geqslant 11$ were interviewed at home and assessed using the Mini-Neuropsychiatric Interview (MINI) (Lecrubier *et al.* 1997) to diagnose a major depressive episode, the Structured Interview Guide for the 17-item version of the Hamilton Depression Rating Scale (SIGH-D, Williams, 1988; HDRS, Hamilton, 1967) and the 13-item version of the Beck Depression Inventory (BDI) (Beck *et al.* 1988). Subjects with a major depressive episode in the prevention group were asked to participate in a programme of between five and eight 1 h weekly home visits. Written informed consent was obtained. This home-based treatment integrated the four components (supportive, educational, cognitive-behavioural and psychodynamic), which were described in a treatment guide that we developed. The objectives of the programme were to establish a relationship of trust with the mother, to provide guidance for infant behaviour problems and enhance self-esteem and confidence by reinforcement of success, to explore and develop appropriate coping with ambivalence toward motherhood and the infant, interpersonal conflicts with the partner and the extended family, and role transitions problems. The objectives of the cognitive-behavioural component were to enhance cognitive skills in detection, evaluation and modification of dysfunctional thoughts, to encourage self-reinforcement and generation of positive coping statements, to develop problem-solving abilities through teaching how to apply structured problem-solving self-instructions to difficult situations, and to improve social-skills through role-playing exercises (Beck *et al.* 1979; D'Zurilla, 1986). The psychodynamic component centered on recognition and management of maternal ambivalence. The main psychodynamic conflicts in post-partum depression involve repression/denial of anger against the infant. The aim of the psychodynamic component was to help the subject acknowledge her ambivalence and link it with her personal history, in particular Oedipal and separation–individuation conflicts. All sessions were audiotaped. Therapists, who had implemented the prevention session already, participated in didactic and clinical training including discussions and role-playing exercises. Weekly supervision was provided to ensure therapist adherence to the treatment guide.

During the period 10 to 12 weeks post-partum, once the treatment had been completed in the intervention group, subjects in both groups were assessed using the MINI, the SIGH-D and the HDRS; the BDI, and the EPDS were also given during a home-visit implemented by the same clinical therapist with whom the subject became acquainted during the first meeting at the clinic. The decision not to use independent evaluators was aimed at reducing drop-out rates, particularly in the control group. We felt that

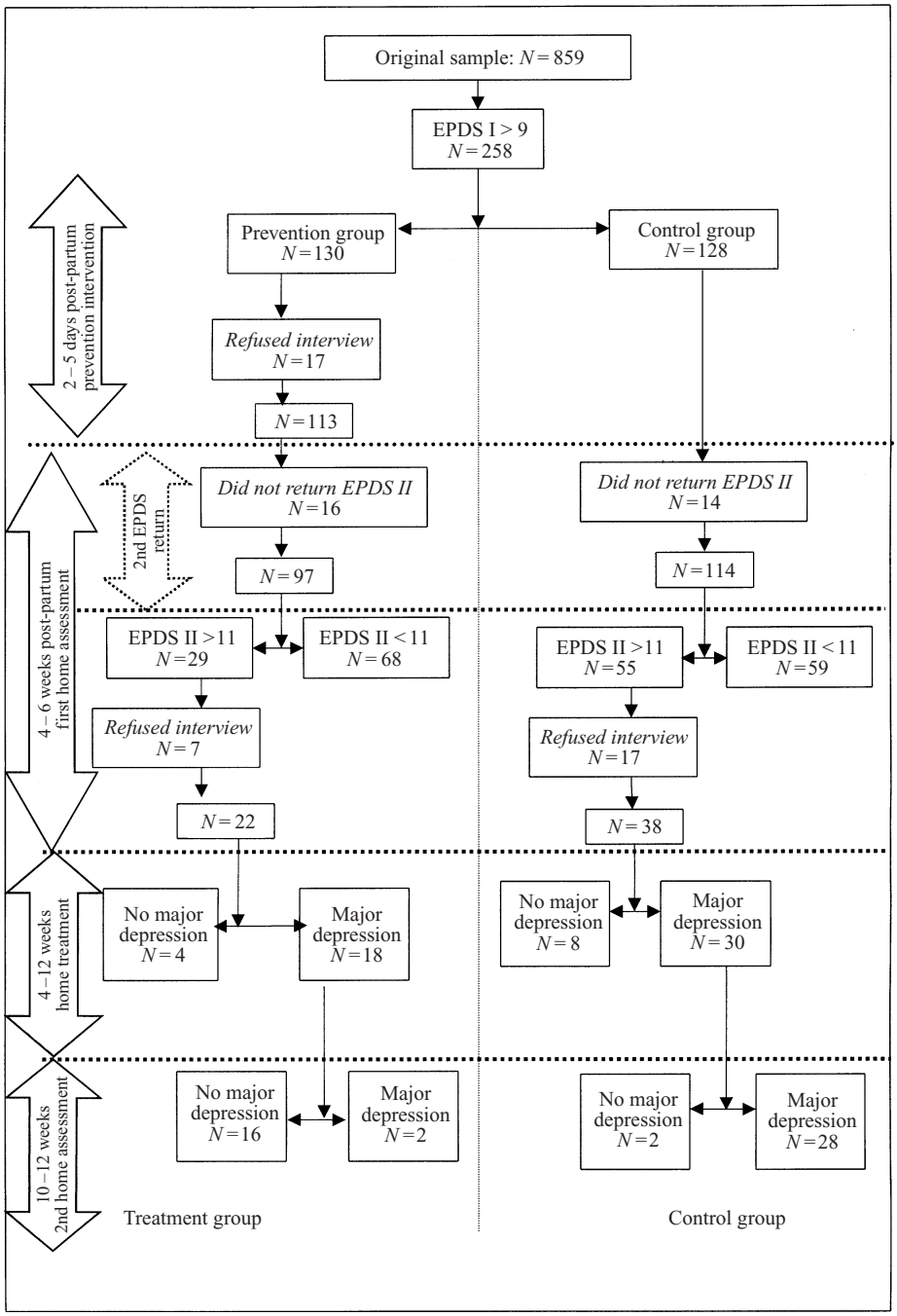

FIG. 1. Flow diagram for subjects through all study phases.

the acceptability of a home-visit evaluation would be enhanced by such a disposition.

No women in both treated and control group received antidepressant therapy before the last assessment. This is not surprising given the low acceptability of antidepressant therapy in French

post-partum women (Chabrol *et al.* 2001). Women in both groups benefited equally from the usual contacts with health services for post-partum women.

Precautions were taken to ensure that women in the control group who required urgent treatment during the trial could receive it. The informed consent forms specified that participants in the control group had the right to withdraw from protocol if they felt the need of an active intervention, in both parts of the study. In the first part of the study, they were given a phone number to contact the student they met at the clinic. In the second part of the study, depressed women in the control group were called each week for a brief assessment by the student who conducted the at-home assessment to evaluate the subject's ability to wait for treatment. Women who were depressed in the control group or in the treatment group at the last assessment were directed to an appropriate treatment.

A χ^2 test was employed to compare the frequencies of major depression and the recovery and response to treatment rates in the intervention and control groups. Repeated-measures multivariate and univariate analyses of variance (MANOVA and ANOVA) were used to examine group differences. An ANOVA was conducted to evaluate the prevention programme. To evaluate the home-visit programme, all outcome measures (HDRS, BDI, EPDS) were entered in one MANOVA. ANOVAS were performed for each outcome measure. An independent samples *t* test was used to compare the two groups on outcome measures. All statistical tests were two-tailed and used an α level of 0·05.

RESULTS

Fig. 1 shows the flow diagram of subjects through all study phases.

Evaluation of the efficacy of the prevention intervention

Among the 859 subjects, 258 (30%) had EPDS scores of $\geqslant 9$ in the first days post-partum. Among the 130 subjects eligible for the prevention group, 17 (13%) declined to participate. All subjects eligible for the control group agreed to participate. The prevention group included 113 subjects (mean age = 30·3, S.D. = 4) and the control group, 128 subjects (mean age = 29·6, S.D. = 5). Thirty subjects, 16 (14%) in the prevention group and 14 (11%) in the control group, did not return the EPDS. Thus, the study compared the outcome of 97 treated subjects to 114 control subjects. Table 1 shows the demographic and clinical characteristics of these subjects. None of the differences was statistically significant. Altogether the drop-out rates (refusals plus no return of the second EPDS) in the first part of the study were 25·4% (33/130) in the intervention group and 10·9% (14/128) in the control group. There was no significant difference between drop-outs and completers on any demographic or clinical variables.

At 4 to 6 weeks post-partum, subjects in the prevention group had significant reduction in the frequency of probable depression, as defined by a score of $\geqslant 11$ on the EPDS. EPDS scores suggested a probable depression in 29 subjects of the prevention group (30·2%) *versus* 55 subjects of the control group (48·2%) ($\chi^2 = 7{\cdot}36$, df = 1, $P = 0{\cdot}0067$). The repeated-measures ANOVA revealed a significant group × assessment occasion interaction ($F_{1,212} = 30{\cdot}9$, $P < 0{\cdot}0000001$). The intensity of depressive symptoms measured by the mean score on the EPDS was significantly lower in the prevention group than in the control group (8·5, S.D. = 4 *v.* 10·3, S.D. = 4·4, $t = 3{\cdot}06$, df = 209, $P = 0{\cdot}0024$). However, these analyses indicated a medium effect size only (ES = 0·42).

An 'intention to treat' analysis was also performed, in which all subjects with an EPDS score $\geqslant 9$ in the first days post-partum were included. It comprised both subjects who refused interview and subjects who did not return the second EPDS. For these subjects, the first EPDS scores were carried forward. Despite this, a repeated-measures analysis of variance revealed a significant group × assessment interaction in favour of prevention ($F_{1,255} = 6{\cdot}8$, $P < 0{\cdot}01$).

Evaluation of the efficacy of the treatment for post-partum depression

Twenty-two (76%) of the subjects with probable depression, who were in the prevention group, accepted participation in the home visit programme of evaluation and treatment. Among the subjects with probable depression in the

Table 1. *Demographic and clinical characteristics of participants*

	Prevention		Home-treatment	
	Prevention group ($N = 97$)	Control group ($N = 114$)	Treated group ($N = 18$)	Control group ($N = 30$)
Mean age (S.D.)	30·4 (4)	29·6 (5)	30·5 (4·3)	30 (5)
Parity, % primiparous	46·6	48·4	66·7	61·8
Mean number of children, *N*	1·4	1·5	1·4	1·6
Type of delivery				
Spontaneous vertex, %	76·3	79·7	85·5	75
Caesarean section, %	23·7	20	14·5	25
Marital status				
Single, %	5	0	0	0
Married/Cohabiting, %	95	100	100	100
Employed, %	96	84·5	75	83·8

None of these differences was statistically significant.

Table 2. *Evaluation of the home-intervention: baseline and outcome HDRS, BDI, EPDS scores (mean ± S.D.) in the treated and control subjects with major depressive episode*

	Treated group ($N = 18$)	Control group ($N = 30$)	*t*	df	*P*
Baseline*					
HDRS	16·4 ± 4·5	17·2 ± 4·4	0·56	49	0·57
BDI	16·8 ± 3·9	16·7 ± 3·9	0·09	49	0·92
EPDS	12·8 ± 3·7	13·7 ± 3	0·93	49	0·35
Outcome†					
HDRS	5·7 ± 3·3	16·2 ± 4·5	8·4	49	< 0·0001
BDI	4·7 ± 3	15·7 ± 4·4	9	49	< 0·0001
EPDS	5·9 ± 2·7	13·7 ± 3·6	7·7	49	< 0·0001

* 4–12 weeks post-partum.
† 10–12 weeks post-partum.

control group, 38 (69 %) agreed to be evaluated at home. Among the 22 subjects with probable depression in the prevention group, 18 (85·7 %) met the DSM-IV criteria for a major depressive episode *versus* 30 (79 %) of the subjects in the control group ($\chi^2 = 0{\cdot}08$, $P = 0{\cdot}77$). Table 1 shows the demographic and clinical characteristics of these subjects. None of the differences was statistically significant. There were no significant differences between drop-outs and completers on any demographic or clinical variables.

Table 2 presents the baseline HDRS, BDI and EPDS scores that were consistent with mild to moderate depression. No significant difference was observed between the two groups on all the rating scales. The correlation between HDRS and BDI scores was high ($r = 0{\cdot}91$, $P < 0{\cdot}05$).

The mean number of home visits in the treated group was 6·1 (S.D. = 1·6). All subjects in both groups completed the protocol. The MANOVA detected a significant group × assessment occasion interaction in favour of treatment (Wilks $\lambda = 0{\cdot}43$, Rao $R_{3,54} = 24{\cdot}5$, $P < 0{\cdot}0000001$). Repeated-measures ANOVAs showed a significant group × assessment interaction for each treatment outcome: HDRS ($F_{1,57} = 62{\cdot}1$, $P < 0{\cdot}0000001$); BDI ($F_{1,57} = 48{\cdot}4$, $P < 0{\cdot}0000001$); EPDS ($F_{1,57} = 42{\cdot}7$, $P < 0{\cdot}0000001$). Table 2 presents the depression outcomes. There were significant differences between the two groups on all rating scales. The correlation between HDRS and BDI scores was high ($r = 0{\cdot}89$, $P < 0{\cdot}05$).

Recovery and response to treatment rates are shown in Table 3. Recovery was defined as an HDRS score of $\leqslant 6$ or a BDI score of $\leqslant 3$. Recovery rates were significantly greater in the treated group than in the control group. According to the HDRS scores, recovery rates were

Table 3. *Evaluation of the home-intervention for post-partum depression: recovery and response to treatment rates*

	Treated group ($N = 18$) N (%)	Control group ($N = 30$) N (%)	χ^2	P
Recovery (HDRS < 7)	12 (66·6)	2 (6·6)	16·8	< 0·0001
Recovery (BDI < 4)	11 (61·1)	1 (3·3)	17·7	< 0·0001
Reduction of HDRS scores ⩾ 50%	15 (83·3)	4 (13·3)	20·2	< 0·0001
Reduction of BDI scores ⩾ 50%	16 (88·8)	4 (13·3)	23·4	< 0·0001
Reduction of EPDS scores ⩾ 50%	13 (72·2)	1 (3·3)	22·6	< 0·0001

66·6% for the treated group *versus* 6·6% for the control group. Response to treatment was defined as ⩾ 50% reduction in symptoms. Based on HDRS, BDI and EPDS scores, a significantly greater proportion of subjects in the intervention group responded to treatment than subjects in the control group. A clearly therapeutic response to treatment was observed in the treated group with a mean reduction in HDRS score of 10·2 (S.D. = 6·7) from baseline compared with the control group (mean = 1·3, S.D. = 3·3) ($t = 6·2$, df = 49, $P < 0·00001$).

An 'intention to treat' analysis was also performed, in which all subjects with an EPDS score ⩾ 11 during the period 4 to 6 weeks post-partum were included. It comprised both subjects who refused interview and subjects with no major depression on the MINI. For these subjects, the second EPDS scores were carried forward. Despite this, a repeated-measures analysis of variance revealed a significant group × assessment interaction in favour of treatment ($F_{1,84} = 32·1$, $P < 0·0000001$).

DISCUSSION

To our knowledge, the present study is one of the first to provide a systematic examination of a well-defined early intervention in a relatively large community sample and is the first to evaluate a structured programme for prevention and treatment of post-partum depression. The prevention intervention resulted in a significant reduction in depressive symptoms and in the frequency of probable depression at 4 to 6 weeks post-partum. However, the effect size was only medium. This result suggests that the prevention intervention did not have a clinically significant effect on the whole prevention group. This confirmed the necessity of adding a treatment intervention for the subjects who developed a post-partum depression despite prevention. The home-based treatment significantly reduced depressive symptoms relative to the control group as attested by the proportion of women who no longer met DSM-IV criteria for major depressive disorder and who met HRSD and BDI criteria for recovery and for response to treatment. Women in the control showed little improvement during the 5 to 8 weeks between the two assessments. These findings suggest that this programme is an efficacious mean of prevention and treatment for post-partum depression. Altogether the drop-out rates (refusals plus no return of the second EPDS) in the first part of the study was 25·4% in the prevention group. Refusals rate was 24% in the home-based treatment and no drop-outs from therapy occurred. These findings suggest that this programme had a reasonable acceptability. They cannot be directly compared with the two largest recent studies where decline in participation rates were respectively 53% and 49% and drop-out rates were 29·8% and 20%, because the times chosen for measuring these differed (Appleby *et al.* 1997; O'Hara *et al.* 2000). The brief prevention intervention had the advantage of developing a collaborative relationship with the therapist facilitating the organization of a treatment if depression appeared. Home-visits are a convenient way of treatment for post-partum depressed women who are often tired and overwhelmed. This prevention and treatment programme might also have high applicability as all mothers could be routinely contacted while still in the maternity hospital or clinic. Moreover, it does not require experienced therapists, having shown efficacy being implemented by inexperienced but trained therapists.

One potential limitation of this study is that the outcome clinical evaluation and the treat-

ment were implemented by the same clinical therapist that the subject became acquainted with during the first meeting at the clinic. We chose not to use independent evaluators for two reasons. First, we thought that it would have been almost impossible to keep the interviewers blind to the treatment condition when one group was receiving treatment and other group was not, given that subjects could reveal whether or not they were receiving treatment. Secondly, we felt that this disposition where evaluators and subjects became acquainted could enhance the acceptability of the programme and reduce attrition rates. For the same reasons, a non-blind assessment was also chosen in a recent study of interpersonal therapy for post-partum depression (O'Hara *et al*. 2000). Moreover, O'Hara *et al*. had verified that the bias due to this procedure was negligible (by blind assessments of the tapes of the therapists' assessments). As in their study, the low overall decline in participation and dropout rate in our study suggests the usefulness of therapists' assessments. The fact that BDI and HDRS scores were highly correlated and gave similar results suggests that the lack of an independent evaluator did not compromise the reliability of HDRS scores.

Another limitation of the study is that the procedure did not allow us to know the time of onset of these depressions (e.g. it did not allow for identification of depression evolving continuously after delivery or exacerbation of prepartum depression after delivery). A consequence is that the preventive intervention was actually curative for some women.

The sample size in the second part of the study is quite small. This may reduce the generalizability of the results. It should be noted that major depressions were of mild to moderate severity. It is likely that our results cannot be generalized to more severe forms of post-partum depression.

Another limitation is the lack of a follow-up study. This limitation is common to other treatment studies in post-partum depression. Further studies are needed to assess the efficacy of actual treatments in prevention of relapse and recurrence of depression and in the prevention of emotional disorders in children.

The findings of this study indicate that a programme based on an intervention at obstetric clinics and on home visits is reasonably efficacious and well-accepted for the prevention, detection and treatment of post-partum depression. The combination of early prevention and treatment might be a solution to the low detection and compliance to treatment rates in post-partum depression.

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