



A randomized controlled trial of psychological interventions for postnatal depression

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Objectives. First, to establish the efficacy of psychological interventions versus routine primary care for the management of postnatal depression (PND). Secondly, to provide a direct comparison of cognitive-behavioural therapy (CBT) versus counselling and, finally, to compare the relative value of group and individual delivery formats.

Design. The study involved 192 depressed women drawn from a large community screening programme in Melbourne, Australia and allocated to cognitive behaviour therapy, counselling, or routine primary care. Baseline and post-intervention measures of depression and anxiety were collected in the form of validated self-report inventories.

Method. Women were screened in the community and diagnosis of depression confirmed with a standardized psychiatric interview. Interventions were of 12 weeks duration, including three partner sessions, and adhered to a structured manual.

Results. Psychological intervention *per se* was superior to routine care in terms of reductions in both depression and anxiety following intervention.

Conclusions. For those women with PND, psychological intervention is a better option than routine care, leading to clinically significant reduction of symptoms. Counselling may be as effective as group cognitive behaviour therapy. The benefits of psychological intervention may be maximized by being delivered on a one-to-one basis.

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Postnatal depression (PND) affects 10–20% of mothers (e.g. Appleby, Gregoire, Platz, Prince, & Kumar, 1994). Most women recover within 6 months, but others continue to show evidence of subclinical depressive symptoms for up to 2 years (Campbell, Cohn, Flanagan, Popper, & Meyers, 1992). Potentially serious sequelae include marital conflict, disturbance in mother–child relationships, and later problems in child development (e.g. Murray & Cooper, 1997; Milgrom, Westley, & Gemmill, 2004). The most widely accessible therapy for depression is antidepressant medication but there are problems associated with this approach in the perinatal period: not least the fact that a high proportion of women are unwilling to take medication, often with concerns over side-effects and breast-feeding (Appleby, Warner, Whitton, & Faragher, 1997).

On balance, there is now reasonable evidence from several controlled trials that psychological interventions for PND are effective, specifically: (a) counselling, (b) cognitive-behavioural therapy (CBT), and (c) psychodynamic/interpersonal therapies. Holden, Sagovsky, and Cox (1989) and Wickberg and Hwang (1996) demonstrated the efficacy of non-directive individual counselling. Appleby *et al.* (1997) found six sessions of counselling superior to one and as effective as an antidepressant (flouxetine). O'Hara, Stuart, Gorman, and Wenzel (2000) demonstrated that interpersonal psychotherapy was superior to a wait list. Prendergast and Austin (2001) compared CBT with standard care and found no significant difference, while Honey, Bennett, and Morgan (2002) report that group-based psycho-education, including cognitive-behavioural techniques, was superior to routine care. Chabot *et al.* (2002) used 'preventative' CBT, followed by both CBT and psychodynamic therapy for women who developed major depression. Both prevention and intervention proved effective.

It seems apparent that we particularly lack direct comparisons of CBT for PND versus the less specialized counselling-based techniques. In a rare, direct comparison of alternative psychological interventions CBT, psychodynamic therapy, non-directive counselling, and routine care were each evaluated simultaneously (Cooper, Murray, Wilson, & Romaniuk, 2003). However, intervention was primarily directed at problems in managing infants rather than at maternal depression. Given the need for treatments that can be delivered by a range of professionals, more comparative studies of this kind are essential.

Furthermore, in many intervention studies reported in this area, formal processes of clinical diagnosis and validated clinical measures of depressive symptomatology are lacking. Similarly, the study samples often represent demographically or psychiatrically narrow populations and the poor availability of manualized intervention materials and the specialized skills needed for delivery, make replication in primary health care settings difficult.

In this study, we evaluated (in a broad, representative community sample) three manualized psychological interventions developed specifically to meet the needs of women with PND. One intervention was a group-based CBT programme, the other two interventions involved counselling administered in either group or individual formats. Previous work (e.g. Meager & Milgrom, 1996) had shown group-based CBT to be effective and we wished to compare this more specialist intervention with group-based and individually delivered counselling. The skill sets necessary to deliver the counselling interventions are more easily transferable to a broad range of professionals than those required for the CBT programme. In practice, individual or group formats have different pros and cons that must be weighed in the overall context of tight resource constraints. For example, whilst a group-based format can offer a more efficient use of therapist

time, an individual approach may be simpler to implement or be more (or less) acceptable to individual women. We therefore set out to compare the efficacy of these counselling formats to help better inform the choice between them in practice. Interventions were assessed in a clinical setting at the Heidelberg Repatriation Hospital in Melbourne, Australia, one of the largest providers of specific, psychotherapeutic PND intervention programs in the state. The routine care provided via the state's universal Maternal and Child Health Service acted as a control condition. We aimed to assess the effects of intervention on both anxiety and depression as pathological anxiety is a frequent accompaniment to PND, but has not often been addressed in clinical intervention trials.

We specified three *a priori* null hypotheses as follows:

Hypothesis 1. Psychological intervention is no different than primary care.

Hypothesis 2. Counselling is no different than CBT.

Hypothesis 3. Individual and group-based counselling are both equally effective.

As a relationship between perceived social support and PND has been demonstrated in a number of studies (e.g. Gottlieb & Mendelsohn, 1995), measures of social support are also reported here.

Method

Sample

Inclusion criteria were: DSM-IV diagnosis of depression; 37–42 week pregnancy; infant birth-weight 2.5 kg and above; no congenital abnormality; no major health problem, and no concurrent major psychiatric disorder. Exclusion criteria were: depression affecting competence to give informed consent (e.g. psychotic depression); risk requiring crisis management; participation in other psychological programmes and significant difficulty with English.

Procedure

Recruitment was via a community screening programme (Milgrom, Ericksen, Negri, & Gemmill *et al.*, 2005) conducted at 47 Maternal and Child Health Centres in northern metropolitan Melbourne and rural eastern Victoria. These centres have contact with all newly delivered mothers and are well placed to sample from a wide demographic and socio-geographic range. Women attending 6 to 18 week postnatal consultations were invited to take part in 'a study investigating the best ways to identify and treat postnatal depression' and were asked to complete the Edinburgh Postnatal Depression Scale as the first stage of this (EPDS: Cox, Holden, & Sagovsky, 1987). The EPDS is a validated, widely used 10-item scale developed specifically to screen women for PND. Women gave written consent for this initial screening stage after reading a participant information sheet. Nurses conducting the screening were not involved in the allocation process and were blind to the allocation method.

In total, 4,148 women completed the EPDS. Of these, 533 scored above the cut-off of 12 and over (Gerrard *et al.*, 1994), and 356 of these agreed to clinical assessment with a psychologist. The assessment used the Composite International Diagnostic Interview

(CIDI) to yield DSM-IV diagnoses of minor or major depression (World Health Organization, 1993). Of those assessed, 77 failed to meet DSM-IV criteria, 65 failed on other inclusion criteria, and 22 women declined participation (see Fig. 1).

Potential recruits were aware that they could not choose a particular intervention and that participation involved regular time commitments. All baseline depression and anxiety data and fully informed, written consent were gathered prior to treatment allocation. Post-intervention data were collected 12 weeks after treatment began with a follow-up after 12 months.

Treatment allocation

In total, 192 women meeting inclusion criteria consented to random allocation between one of four treatment conditions: group-based CBT ($N = 46$ allocated); group-based counselling ($N = 47$ allocated); individual counselling ($N = 66$ allocated), and routine primary care ($N = 33$ allocated). The group-based nature of some interventions conflicted with the ethical need to ensure an upper limit on clinic waiting times and this made individual randomization unsuitable. Instead, allocation was cycled to allow recruitment of sufficient participants to form viable groups (between 5 and 10 women). At each cycle of recruitment, treatment allocation for the newly recruited cohort was then effected by a process of drawing lots (one coded slip of paper drawn from a bag containing multiple slips coded in equal number for each of the four treatment conditions). This resulted in some inequality of sample sizes between conditions, and recruitment continued until the minimum required sample size was achieved in all treatment conditions. To preclude conscious or unconscious selection bias, all potential participants were kept blinded to treatment until the point of allocation. For obvious reasons in a trial of psychological interventions, treatment allocation could not be concealed further. Psychological assessments were conducted at a different venue (a hospital clinic) from the initial screening (maternal and child health centres). Every effort was made to ensure that clinicians conducting psychological assessments remained blind to allocation, and the importance of remaining blind was regularly impressed upon all of the professionals involved. Figure 1 shows the flow of participants through the study in detail.

Psychological interventions

Full details of the psychological interventions are in Milgrom, Martin, and Negri (1999). The three interventions had a number of features in common. Each was specifically developed to treat PND and each focused on life events, maternal mood, and practical issues. All were clinic-based, delivered according to detailed manuals. The programs consisted of nine, weekly, 90-minute sessions with mothers, and three sessions involving partners. For group interventions (CBT and group-based counselling) each group of 5–10 women was led and facilitated by a senior therapist. To ensure treatment integrity, therapists completed session checklists, recorded comments on individual client sheets after each session and ensured that all prescribed content was covered.

Group-based cognitive behaviour therapy (CBT)

This programme was developed by adapting Lewinsohn's *Coping with Depression Course* (Lewinsohn, Antonuccio, Steinmetz, & Teri, 1984; Lewinsohn, Munoz, Youngren, & Zeiss, 1992). Pilot results (Negri, 1999) suggested a number of refinements. The course is modified to meet the unique needs of new mothers by

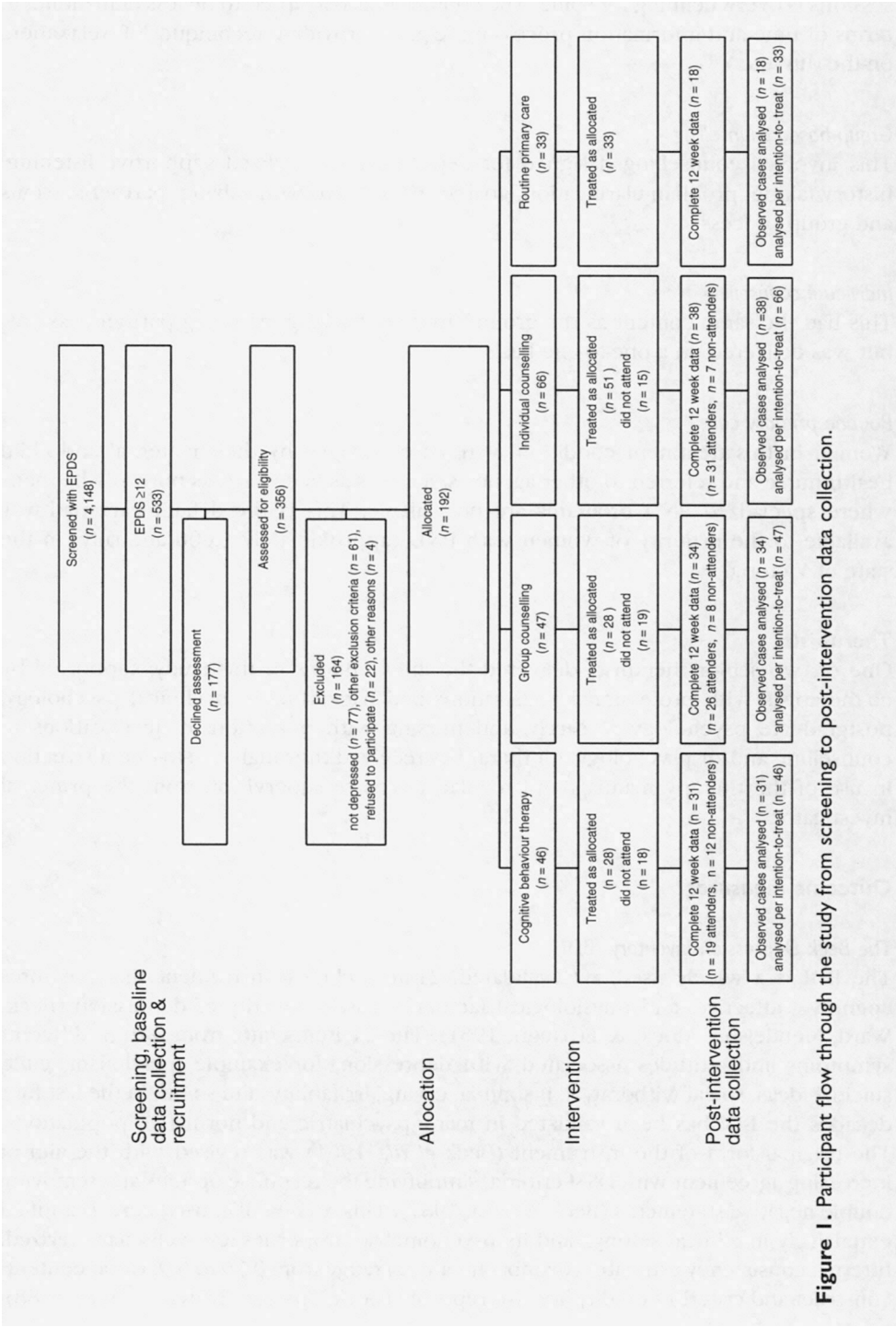


Figure 1. Participant flow through the study from screening to post-intervention data collection.

addition of partner sessions and modules on family of origin issues. Also, the order of sessions is changed. For example, relaxation is deferred in favour of earlier introduction of pleasant activities and time management, as most mothers commencing the course are experiencing life as difficult, and organizing themselves and their babies to attend sessions is overwhelming for some. The content is also adapted to be less demanding in terms of time and information processing (e.g. by providing techniques of 'relaxation-on-the-run' etc.).

Group-based counselling

This involved counselling designed for depression and utilized supportive listening, history taking, problem clarification, goal formation, problem solving, partner sessions and group process.

Individual counselling

This had the same content as the group-based counselling including partner sessions, but was delivered on a one-to-one basis.

Routine primary care

Women in this treatment condition were case-managed by their maternal and child health nurse and referred to other agencies/services as necessary, as normally happens where specialized PND programs are unavailable. This is the default care pathway available to the majority of women with PND (approximately 6,000 annually) in the state of Victoria.

Therapists

One of two senior therapists delivered the interventions in this study, supported by co-therapists with professional registrations and backgrounds in clinical psychology, postgraduate psychology research, and nursing with postgraduate qualifications in counselling and/or psychology. All therapists received thorough one-to-one instruction in use of the therapy manuals and regular, intensive supervision from the principal investigator.

Outcome measures

The Beck Depression Inventory (BDI)

The BDI is a widely used, well-validated, 21-item clinical instrument that measures cognitive, affective, and physiological factors to assess severity of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The 21 items rate, from 0 to 3, different symptoms and attitudes associated with depression, for example, pessimism, guilt, suicidal ideas, social withdrawal, insomnia, crying, irritability, and so on. In the last four decades the BDI has been validated in many psychiatric and normative populations. The original form of the instrument (Beck *et al.*, 1961) was revised with the aim of increasing agreement with DSM criteria, simplifying the response options and removing double negative statements (Beck & Steer, 1987). This revised BDI, used here, is applied extensively in clinical settings and its psychometric properties are well characterized. Internal consistency estimates (Cronbach's alpha) range from 0.79 to 0.9. Good content, construct and criterion validity are also reported (Beck, Epstein, Brown, & Steer, 1988).

Beck Anxiety Inventory (BAI)

The BAI (Beck *et al.*, 1988) is a 21-item instrument for measuring anxiety, designed for use in conjunction with the BDI.

Social Provisions Scale (SPS)

The SPS (Cutrona, 1984) is a 24-item scale for measuring social support. Demographic data including age, occupation, and marital status were also gathered at assessment.

Power and sample size

We calculated the sample size necessary to detect a clinically meaningful difference, δ , as significant at the 0.05 level with a power of 0.8 as:

$$N = 2(0.84 + 1.96)^2 * (\sigma/\delta)^2$$

where σ is the standard deviation and 0.84 and 1.96 are the 0.8 and the 0.975 quantiles of the standard normal distribution, respectively. Pilot data from 56 depressed women (Negri, 1999) provided relevant parameter estimates (baseline BDI = 23, $\sigma = 8.09$). There are several possible ways to define a 'clinically meaningful' difference. For example, an arbitrary factorial threshold of score change could be applied (e.g. 1.5, 2 etc.). Alternatively, a reduction of 20% or more in BDI scores would always ensure transition between the symptomatic categories defined by Beck, Rush, Shaw, and Emery (1979). For this study, we applied the following rationale. Based on the average BDI score at the time of DSM-IV diagnosis (BDI = 23, $\sigma = 8.09$) an average between-group difference (δ) of 6.5 points would take scores below Beck *et al.*'s threshold of 'clinical' depression (BDI = 17) and into the 'mild-mood disturbance' category. This is close to the between-group difference in post-intervention BDI scores (5.5 points after 8 weeks of interpersonal psychotherapy) detected by O'Hara *et al.* (2000). To detect an average between-group change of 6.5 points, with a power of 0.8 at $\alpha = 0.05$, the required sample size per treatment condition is therefore:

$$N = 15.7(8.09/6.5)^2 = 24.3, \text{ which rounds to } 24.$$

For prudence, we recruited a minimum of 33 participants per treatment, in order to provide a margin of error greater than one-third.

Statistical analysis

The inclusion of both group-based and individually delivered interventions, as well as the involvement of two leading and several supporting therapists, introduces various levels of complexity into the modelling of these data. Following Rubin (1987) we considered several hierarchical models of the form:

$$y_i = a_1x_1 + a_2x_2 + b_m + \varepsilon_{mi} + \varepsilon_i,$$

where $\varepsilon_i \sim N(0, \sigma^2)$, that is, σ^2 is the residual variance, and $(\varepsilon_{1i}, \varepsilon_{2i}, \varepsilon_{3i}, \varepsilon_{4i}) \sim N(0, \Sigma)$ are the residuals associated with different therapists, b_m is the main effect for treatment m ($m = 1, \dots, 4$), and x_1, x_2 are the covariates of interest.

The various models structured the covariance matrix Σ in different ways: as a full covariance matrix, as a diagonal covariance matrix with differing values along the diagonal and zeros elsewhere, and as a diagonal covariance matrix with the same value along the diagonal. This last model is reported here as neither former model could be fitted without substantially relaxing the convergence criteria.

For each outcome measure (post-intervention BDI and BAI scores), we fitted models that controlled for baseline values as covariates. Assigning the four treatments linear contrast coefficients whose cross-products summed to zero, we estimated orthogonal sets of three treatment contrasts thus:

$$\begin{aligned} c_1 &= (-b_1 - b_2 - b_3 + 3b_4)/3, \\ c_2 &= (-2b_1 + b_2 + b_3)/2, \\ c_3 &= b_2 - b_3. \end{aligned}$$

Hence, c_1 is the average difference between routine primary care and the three interventions combined and tests the effect of psychological intervention *per se* (i.e. null Hypothesis 1). Next, c_2 is the average difference between CBT and counselling, yielding a direct comparison of the relative efficacy of these two modes of intervention (null Hypothesis 2). Finally, c_3 represents the difference between group and individual formats as measured in the overall context of a counselling intervention (null Hypothesis 3).

We adhered to intention-to-treat principles as follows. Analyses were executed twice: once using only observed cases (121/192 possible cases), and once using multiple imputation under multivariate normal assumptions using methods given by Schaffer (1997, 1999), employing available demographic and psychometric data.

Last, we conducted analyses to test the assumption that missing data were missing at random. Computations were carried out in SAS version 8 and in WinBugs 1.4 (Speigelhalter, Thomas, & Best, 2000).

Results

Table 1 gives baseline characteristics for the 192 allocated women.

Compliance

Of 159 individuals allocated to the three psychological interventions, 52 did not attend the allocated treatment. By definition, non-attendance was not an issue for those participants allocated to routine primary care. In total 121 of 192 allocated participants completed post-intervention measures (refer back to Fig. 1).

Table 1. Baseline characteristics of participants

EPDS score at screening (SD)	16.6 (4.3)
Mother's age in years (SD)	29.7 years (5.4)
Infant age (SD)	18.3 weeks (10.0)
Mean number of children (SD)	1.8 (0.8)
Family income in Australian dollars $\times 10^3$ (SD)	41.4 (20.5)
Percentage living with a partner	81.4%
Percentage with 12 or more years of school	62.7%
Percentage with a higher education	30.5%
Percentage with a non-English first language	2.7%

Outcome analyses

Results for the main outcome variable (post-intervention BDI) and for the anxiety measure are shown in Tables 2 to 5, and in Figures 2 and 3. Models that controlled for the number of weeks postpartum (infant age) as a covariate found that this exerted no

Table 2. Depression. Contrast estimates for observed cases

	Difference in BDI scores	SE	df	p value
Baseline score	.580	.108	82	<.0001
c ₁	6.94	2.29	34	.005
c ₂	-.065	1.86	34	.97
c ₃	5.17	2.06	34	.02

Table 3. Depression. Contrast estimates from 41 sets of imputations

	Difference in BDI scores	SE	df	p value
Baseline score	.510	.11	290.2	<.0001
c ₁	4.06	2.08	556.8	.05
c ₂	-.75	1.83	673.7	.68
c ₃	2.94	1.99	866.2	.14

Table 4. Anxiety. Contrast estimates for observed cases

	Difference in BAI scores	SE	df	p value
Baseline score	.54	.079	53	<.0001
c ₁	7.86	2.25	27	<.01
c ₂	.03	2.12	27	.99
c ₃	2.41	2.46	27	.34

Table 5. Anxiety. Contrast estimates from 41 sets of imputations

	Difference in BAI scores	SE	df	p-value
Baseline score	.55	.077	361.7	<.0001
c ₁	4.15	1.99	667.5	.037
c ₂	-.25	1.80	595.3	.89
c ₃	1.52	2.08	402.8	.46

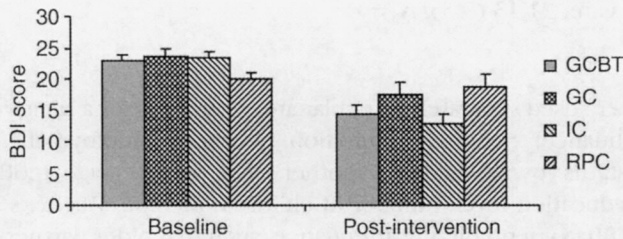


Figure 2. Mean BDI scores (+SE) for CBT, group counselling (GC), individual counselling (IC) and routine primary care (RPC) conditions at baseline and after intervention (observed cases).

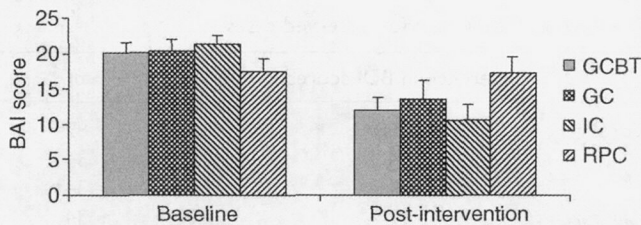


Figure 3. Mean BAI scores (+SE) for CBT, group counselling (GC), individual counselling (IC) and routine primary care (RPC) conditions at baseline and after intervention (observed cases).

measurable effect and it was excluded from subsequent models. In terms of both depression and anxiety, the observed case analyses (121 cases of 192 recruited, see Fig. 1) show psychological intervention to be more effective than routine primary care, by clinically and statistically significant margins (around 7 points on the BDI and 8 points on the BAI). These results remain qualitatively the same in analyses using multiple imputation, leading us to reject our pre-specified null Hypothesis 1. However, our second null hypothesis, namely that CBT and counselling would be no different, was upheld both for anxiety and depression scores. In the overall context of counselling, an individually delivered course of therapy yielded the best outcome in terms of depression (by 3–5 points on the BDI). Although inclusion of imputed values pushes the significance level of this last contrast below the 90% level, this is not unexpected given the statistical ‘noise’ that all such techniques necessarily introduce. We believe that in practice, most clinicians would consider an 86% probability of a 20% advantage (Fig. 2) to be a sound enough basis on which to choose between alternative therapeutic paths, and that with a larger sample size we would indeed have detected this difference as statistically significant (fresh power calculations employing parameter estimates from the current study suggest group sizes of 98 individuals are required to detect a 3-point difference at $\alpha = 0.05$).

Finally, the percentages of women in each treatment condition whose post-intervention BDI scores fell below the threshold for clinical depression (17) were: CBT, 55%; group counselling, 64%; individual counselling, 59% and routine primary care, 29% (observed cases only).

Follow-up

Obtaining data 12 months post-intervention proved very problematic and only 57 cases are available. These data are too few to analyse usefully, but for completeness, the observed case values for the BDI (*SD*) at 12 months were: CBT, 12.17 (9.1), $N = 12$; group counselling, 13.77 (10.1), $N = 13$; individual counselling, 9.79 (5.9), $N = 24$; routine primary care, 21.13 (9.5), $N = 8$.

Missing data

The following were used separately as explanatory variables for a binary (0,1) coding of participant attendance: treatment condition, partner’s employment status, marital status, housing status (owned/rented), mother’s age, partner’s age, mother’s education level, partner’s education level, number of children, income. Partner’s age was highly significant ($p = .0045$) in predicting attendance, such that older partners (in all cases in this study this meant the father of the infant) carried more chance of non-attendance. We have no explanation (except chance) as to why this is so.

Next, we conducted almost identical analyses for binary codings (0,1) indicating missing values of the 'outcome' variables (BDI and BAI). Again the best predictor of missingness was partner's age, and if this was fitted no other predictor was needed. However, neither the inclusion of partner's age as an imputation variable, nor as an explanatory variable made any difference to our contrast estimates, verifying that no systematic bias had been introduced.

Social support

Table 6 shows baseline and post-intervention levels of perceived social support. Whilst all interventions resulted in increased mean levels of support, those depressed women in routine care appeared to feel less supported 12 weeks after diagnosis.

Table 6. Social support before and after intervention (observed cases)

	Group CBT	Group counselling	Individual counselling	Routine primary care
	Social Provision Scale scores (SE)			
Baseline	70.88 (3.00)	68.96 (2.21)	70.23 (2.38)	73.00 (3.22)
Post-intervention	77.44 (2.87)	71.50 (2.26)	76.37 (1.98)	69.13 (2.25)

Discussion

Given the high prevalence of PND, there is a need to validate effective, transferable intervention strategies in community-based samples. Our sample consisted of women with moderately severe PND (mean baseline BDI = 22.8; EPDS = 16.6), similar in magnitude to those described by O'Hara *et al.*, 2000 (BDI = 22.3), Appleby *et al.*, 1997 (EPDS = 16.4) and Honey *et al.*, 2002 (EPDS = 18.7). Changes in depression and anxiety immediately post-intervention significantly differed between psychological intervention versus routine care. These results indicate that clinic-based psychological interventions are effective for PND and anxiety, extending earlier work with CBT-based programs (e.g. Meager & Milgrom, 1996). In the present study we found no evidence that CBT and counselling led to different outcomes in terms of depressive symptoms, and this finding may be important to explore further. Specifically, an equivalence trial (a trial designed to test the null hypothesis that the two interventions are different) would be of interest. This would mean much larger sample sizes than the usual sort of study based around null hypotheses of no difference (Jones, Jarvis, Lewis, & Ebbutt, 1996), but would be an important addition to the literature. Whilst some CBT and counselling skills are transferable to non-psychologists, it is important in practice to identify the most efficacious approach, so that the alleviation of pathology can be maximized in the community as a whole.

Given that poor social support is a known risk factor for PND, if in the absence of interventions women feel increasingly less supported, then future work might focus on how to maximize existing sources of support (i.e. family, friends etc.).

The present study also points to the value of an individual format in counselling. Future work could aim to test the unidirectional (one-tailed) hypothesis that individual counselling is indeed the best format. One interpretation of our findings is that if

individual counselling is superior to group counselling, then individual CBT should likewise be more effective than group CBT. This is speculative however, and must await further research, ideally in the form of a fully cross-factored, randomized controlled trial with format and intervention configured as independent factors. Again, the answer could have very real practical repercussions as, for example, group-based interventions may carry different therapist-related costs or there may be some unforeseen interaction of delivery format and intervention type.

Whilst intervention is superior to routine care, we find nothing in our results to indicate that any particular mode of psychological intervention is best suited to alleviating the anxiety that often accompanies PND. Perhaps the biggest alleviation of anxiety symptoms stems from the act of engaging some kind of active treatment intervention, irrespective of other details. Again, an equivalence trial might yield some useful practical information in this regard.

The attrition rate in this study was quite high, presumably reflecting the fact that participants were recruited by screening and had not proactively nominated their own treatment. Obtaining sufficient follow-up data proved unfeasible and no formal analysis was possible, although group means were all consistent with a lasting intervention effect.

Conclusions

In summary, we confirm that psychotherapeutic interventions (both counselling and CBT) are effective for the treatment of PND. The value of each approach has now been demonstrated in several controlled trials in various countries. Our study indicates that interventions based on a counselling approach may be more effective when delivered on an individual basis and it will be of interest to find out whether this might also be the case for CBT. The efficacy of psychological intervention for PND counters those arguments against universal screening which are based around the claim that no proven treatments are available for identified cases. Such interventions offer an efficacious alternative for the large number of new mothers with moderate-severe PND who, for whatever reason, choose to eschew antidepressant medication. The equivalence or non-equivalence of CBT programs versus counselling-based therapies awaits a formal, empirical test.

Acknowledgements

The research was funded by the National Health & Medical Research Council and the Austin Hospital Medical Research Foundation. Thanks to Caroline De Paola, Jennifer Ericksen, Lyn Littlefield, Rachael McCarthy, and Elizabeth Loughlin. Many thanks also to the women and Maternal and Child Health nurses of Melbourne who made this study possible.

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Received 29 August 2003; revised version received 16 July 2004