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Papers

A controlled study of fluoxetine and cognitive-behavioural counselling in the treatment of postnatal depression

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Abstract

Objective: To study the effectiveness of fluoxetine and cognitive-behavioural counselling in depressive illness in postnatal women: to compare fluoxetine and placebo, six sessions and one session of counselling, and combinations of drugs and counselling.

Design: Randomised, controlled treatment trial, double blind in relation to drug treatment, with four treatment cells: fluoxetine or placebo plus one or six sessions of counselling.

Subjects: 87 women satisfying criteria for depressive illness 6-8 weeks after childbirth, 61 (70%) of whom completed 12 weeks of treatment.

Setting: Community based study in south Manchester.

Main outcome measures: Psychiatric morbidity after 1, 4, and 12 weeks, measured as mean scores and 95% confidence limits on the revised clinical interview schedule, the Edinburgh postnatal depression scale and the Hamilton depression scale.

Results: Highly significant improvement was seen in all four treatment groups. The improvement in subjects receiving fluoxetine was significantly greater than in those receiving placebo. The improvement after six sessions of counselling was significantly greater than after a single session. Interaction between counselling and fluoxetine was not statistically significant. These differences were evident after one week, and improvement in all groups was complete after four weeks.

Conclusions: Both fluoxetine and cognitive-behavioural counselling given as a course of therapy are effective treatments for non-psychotic depression in postnatal women. After an initial session of counselling, additional benefit results from either fluoxetine or further counselling but there seems to be no advantage in receiving both. The choice of treatment may therefore be made by the women themselves.

Introduction

Non-psychotic depressive illness, affecting 8-15% of women in the first few months after childbirth,^{1 2 3 4 5} can lead to chronic or recurrent mood disorder in the mother,² and disturbances in behaviour and cognitive development in the infant.^{6 7} Despite its prevalence and potential

impact, and the increasing practice of identifying cases through screening by health visitors, its treatment has rarely been studied in a controlled trial.

Only one intervention study has been published in which cases were identified by screening a community based population of newly delivered mothers.⁸ This showed a significant improvement in mood in women receiving non-directive counselling from trained health visitors; the counselling was given in an average of 8.8 sessions over three months. An untreated control group showed no improvement. In another placebo controlled study, treatment with oestrogen was found to have improved mood after two months,⁹ although the subjects, being medical referrals, are likely to have been more severely depressed than the majority of community cases.

Anecdotally, women who attend general practitioners with postnatal depression are often treated with a conventional antidepressant, although the anxiety present in many of these patients, the need to avoid oversedation in nursing mothers, the difficulties of prescribing to breastfeeding women, the psychosocial adversity faced by women with postnatal depression,^{2 3 10 11} and the good prognosis of non-psychotic depression in the community¹² make it unclear which, if any, antidepressants are likely to be beneficial. We are not aware of any published trial of antidepressants in this condition, nor of any study that has examined the relative effects of pharmacological and psychological intervention.

We aimed to determine the optimal treatment for non-psychotic depression in childbearing women. The drug used in the study was fluoxetine, a serotonin specific reuptake inhibitor, a class of drugs that is anxiolytic and non-sedating. The psychological treatment was a simple form of counselling based on cognitive-behavioural therapy. All trial subjects received at least one session of counselling, as described below. The hypotheses under test were that six sessions of counselling would be more effective than one; that fluoxetine would be more effective than placebo; and that after one session of counselling, fluoxetine and additional sessions of counselling would be equally effective.

Method

Subjects were women found by screening in an urban health district to be depressed 6-8 weeks after childbirth. From May 1993 to February 1995 women on the maternity wards of two large hospitals in south Manchester were asked to allow assessment of their mood in their homes 6-8 weeks later. This initial approach took place on alternate weekdays; exclusion criteria were inadequate English and living outside the district. The population screened therefore represented a largely unselected systematic sample of newly delivered mothers.

At the screening visit subjects completed the Edinburgh postnatal depression scale,¹³ and those who scored ≥ 10 (a threshold at which sensitivity is 89%¹⁴) were interviewed with the revised clinical interview schedule.¹⁵ Women who scored ≥ 12 on the revised clinical interview schedule,

the threshold for significant psychiatric morbidity, and who satisfied research diagnostic criteria¹⁶ for major or minor depressive disorder, were invited to take part in the treatment trial. The main exclusion criteria were chronic (>2 years) or resistant depression, current drug or alcohol misuse, severe illness requiring close monitoring or hospital admission, and breast feeding. Demographic and obstetric data for all subjects were recorded, and additional clinical information was noted on those who agreed to enter the trial.

Subjects were allocated to one of four treatment groups by using computer generated random numbers, to receive a combination of fluoxetine or placebo, plus either one session or six sessions of counselling. The counselling was derived from cognitive-behavioural therapy and was designed to be delivered by non-specialists in mental health—for example, health visitors—after brief training. Each session was structured to offer reassurance and practical advice on four areas of concern to depressed mothers: feelings of not coping, lack of enjoyable activities, lack of practical support, and caring for any older children. In addition, the first session (in week 1 of the trial), which lasted one hour, allowed women time to describe their current circumstances and emotional state. Subsequent sessions lasted 30 minutes; previously agreed tasks, such as taking the baby to a park, or going out socially, were reviewed. These sessions took place in weeks 2, 3, 5, 7, and 11 of the trial.

There was no "no treatment" group. This was for ethical reasons, and because of previous evidence that non-directive counselling was of benefit.⁸ Our study was intended to develop this finding by examining the relative impact of drug and counselling interventions, and by comparing the effect of counselling given as a single session and as a course of treatment.

The duration of treatment was three months. Follow up assessments of mood took place using the revised clinical interview schedule as the principal outcome measure after 1, 4 and 12 weeks of treatment. Subjects also completed the Edinburgh postnatal depression scale at these times, and were assessed with the Hamilton depression scale,¹⁷ a standard assessment instrument in antidepressant trials, at entry to the trial and at 12 weeks. The assessment interviews were conducted by a psychiatrist blind to subject treatment group. The counselling was delivered by a psychologist with no previous clinical training, supervised by a second psychiatrist; both were blind to drug treatment, as were trial subjects.

Statistical analysis

The three psychiatric measures were analysed separately by analysis of variance with repeated measures over time. The non-repeated factors evaluated were type of drug treatment and number of counselling sessions; the interaction between these was also examined. All three measures followed approximate log normal distributions so were converted to natural logarithms for analysis; the results were detransformed back into their original units for presentation (geometric means with their 95% confidence limits). Two complete analyses were performed; in

the first, only those subjects who completed treatment were included, while in the second ("intention to treat") all subjects who were randomised were included, using last observation carried forward for non-completers.

Results

Subjects

In the 20 month recruitment period 2978 women were eligible to take part in the screening, of whom 2395 (80%) agreed to complete the Edinburgh postnatal depression scale 6-8 weeks later. A total of 503 (21%) scored ≥ 10 on the Edinburgh postnatal depression scale, of whom 406 (81%) agreed to further assessment; 218 (54%) of these were found not to satisfy entry criteria for depression at interview, indicating a low specificity of the Edinburgh postnatal depression scale at this threshold.

We therefore identified 188 confirmed cases of depression (9.7% of initial sample, adjusted for later refusals), of whom 87 agreed to enter the treatment trial. The commonest reason for women to refuse was reluctance to take medication, most commonly because they expected to improve without treatment. The characteristics of the women who entered the trial and those who did not are shown in table 1). Those entering the trial were significantly younger ($P < 0.001$). The characteristics of the four treatment groups are shown in table 2).

Table 1 Characteristics of depressed women who agreed or refused to enter trial of treatment

Characteristic	No agreeing (n=87)	No refusing (n=101)
Single	26	21
Unemployment:		
Subject*	66	67
Partner	22	17
History of subfertility†	3	9
Primiparity	28	36
Unplanned pregnancy	55	58
Complicated pregnancy	26	21
Complicated delivery	18	34
Caesarean section	15	19
Prematurity	15	10

*No job to return to after maternity leave.

†>1 Year failing to conceive before this pregnancy.

Table 2 Characteristics of women in treatment groups

Characteristics;	Fluoxetine plus counselling		Placebo plus counselling	
	1 Session (n=22)	6 Sessions (n=21)	1 Session (n=23)	6 Sessions (n=21)
Mean age (years)	25.7	26.6	23.1	26.0
Single	6	7	8	5
Unemployment:				
Subject*	14	14	20	18
Partner	5	4	5	8
Primiparity	9	4	11	4
Unplanned pregnancy	17	9	13	16
Complicated pregnancy	3	10	6	7
Complicated delivery	2	3	8	5
Caesarean section	2	3	6	4
Prematurity	3	5	3	4
Baby in special care baby unit	4	2	2	3
Major depressive disorder	15	11	13	12
Minor depressive disorder	7	10	10	9
History of postnatal depression	9	8	6	7
History of other depression	6	4	2	1
Family history of postnatal depression	8	2	2	4

Family history of other depression	11	4	8	5
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* No job to return to after maternity leave.

Table 3) shows the number of drop outs, the duration of treatment received, and the reasons for dropping out in each treatment group. Drop out rates were similar in the four groups. Drop outs were younger than subjects who completed the study (23.7 (SD 6.2) years v 26.3 (5.1) years; $t_{85}=2.06$, $P=0.04$) and more likely to have an unemployed partner ($\chi^2=3.8$, $df=1$, $P=0.05$) and to have had a planned pregnancy ($\chi^2=4.6$, $df=1$, $P=0.03$), but the groups did not differ on initial psychiatric morbidity scores, employment, obstetric complications, parity, family history, or personal history of depression, including postnatal depression.

Table 3 Number of dropouts, timing of dropping out, and reasons for dropping out in treatment groups

Characteristics	Fluoxetine plus counselling		Placebo plus counselling		Total
	1 Session	6 Sessions	1 Session	6 Sessions	
No entering trial	22	21	23	21	87
No of dropouts	6	8	6	6	26
Stage of dropout:					
Before 1 week assessment	3	4	3	6	16
Before 4 week assessment	3	5	3	6	17
Before 12 week assessment	6	8	6	6	26
Reason for dropping out:					
No reason given	3	5	2	4	14
Disliked drug	1	1	2	1	5
Side effects		1	2	1	4
Lack of improvement					

Effects of treatment

Tables 4, 5 and 6 show mean scores and their 95% confidence intervals on the three assessment instruments. The results were first analysed for subjects completing 12 weeks of treatment. Highly significant improvements were seen in all four treatment groups. fluoxetine was superior to placebo on all outcome measures. Six sessions of counselling were superior to one session on the revised clinical interview schedule and Hamilton depression scale but not on the Edinburgh postnatal depression scale.

Table 4 Geometric mean scores on revised clinical interview schedule scores (95% confidence intervals) for patients who completed the study [all patients randomised into the study, assessed by intention to treat analysis]

Treatment (drug plus sessions of counselling)	No of patients	Assessment time			
		Baseline	1 Week	4 Weeks	12 Weeks
Fluoxetine:					
Plus 1 session	16 [22]	28.8 (26.4 to 31.4)[29.6 (27.5 to 31.8)]	19.1 (16.0 to 24.9)[21.4 (18.4 to 24.9)]	10.3 (6.5 to 19.1)[13.3 (9.1 to 19.1)]	8.0 (4.4 to 17.6)[11.1 (6.9 to 17.6)]
Plus 6 sessions	13 [21]	26.7 (23.5 to 30.4)[26.8 (23.9 to 30.1)]	13.6 (7.5 to 23.7)[16.5 (11.4 to 23.7)]	6.3 (2.5 to 17.1)[9.9 (5.6 to 17.1)]	7.0 (3.4 to 16.6)[10.5 (6.6 to 16.6)]
Placebo:					
Plus 1 session	17 [23]	30.0 (27.7 to 32.5)[29.3 (27.0 to 31.9)]	23.5 (19.0 to 28.3)[24.0 (20.4 to 28.3)]	17.3 (13.6 to 23.0)[18.9 (15.5 to 23.0)]	17.5 (13.5 to 23.5)[19.1 (15.4 to 23.5)]
Plus 6 sessions	15 [21]	27.1 (24.0 to 30.6)[27.2 (24.7 to 29.9)]	20.5 (16.4 to 25.1)[21.1 (17.7 to 25.1)]	10.7 (7.8 to 17.7)[13.5 (10.2 to 17.7)]	9.9 (6.6 to 18.1)[13.0 (9.2 to 18.1)]
Total fluoxetine	29 [43]	27.8 (25.9 to 29.9)[28.2 (26.4 to 30.1)]	16.4 (12.6 to 22.8)[18.9 (15.6 to 22.8)]	8.3 (5.4 to 15.8)[11.5 (8.4 to 15.8)]	7.6 (5.0 to 14.8)[11.3 (7.9 to 14.8)]
Total placebo	32 [44]	28.6 (26.7 to 30.7)[28.3 (26.6 to 29.6)]	22.1 (19.0 to 22.6)[22.6 (20.1 to 22.6)]	13.8 (11.3 to 16.8)[16.1 (13.6 to 17.1)]	13.4 (10.5 to 15.9)[15.9 (13.1 to 15.9)]

			to 30.1)]	to 25.4)]	to 19.0)]	to 19.3)]
Total 1 session counselling	33 [45]	29.4 (27.8 to 31.1)[29.4 (27.9 to 31.1)]	24.4)[23.7 (20.4 to 25.3)]	17.3)[15.9 (13.0 to 16.5)]	12.1 (8.8 to 11.4 to 18.9)]	
Total 6 sessions counselling	28 [42]	27.0 (24.8 to 29.3)[27.0 (25.1 to 29.0)]	22.5)[18.7 (15.3 to 22.7)]	12.5)[11.6 (8.6 to 15.5)]	8.4 (5.9 to 8.9 to 15.3)]	

Scores ≥ 12 indicate clinically important morbidity.

Table 5 Geometric mean scores on Edinburgh postnatal depression scale (95% confidence intervals) for patients who completed the study [all patients randomised into the study, assessed by intention to treat analysis]

Treatment (drug plus sessions of counselling	No of patients	Assessment time			
		Baseline	1 Week	4 Weeks	12 Weeks
Fluoxetine:					
Plus 1 session	16[22]	16.4 (14.9:18.0)[16.6 (15.4:18.0)]	12.8 (10.7:15.1)[13.2 (11.3:15.4)]	8.1 (6.5:10.0)[9.5 (7.7:11.6)]	5.4 (3.5:8.0)[7.1 (5.0:10.1)]
Plus 6 sessions	13[21]	16.9 (14.7:19.4)[17.7 (16.1:19.5)]	10.9 (7.2:16.1)[12.1 (9.4:15.7)]	5.9 (3.2:10.3)[8.0 (5.2:11.9)]	5.3 (2.5:10.1)[7.5 (4.6:11.8)]
Placebo:					
Plus 1 session	17[23]	17.4 (15.2:19.9)[17.5 (15.8:19.3)]	14.2 (11.5:17.5)[14.4 (12.3:16.9)]	8.7 (5.6:13.2)[9.4 (6.8:13.0)]	9.8 (7.2:13.3)[10.3 (8.1:13.2)]
Plus 6 sessions	15[21]	16.8 (14.6:19.3)[16.4	14.2 (11.8:17.1)[13.1	9.0 (7.0:11.4)[9.8	9.9 (5.5:11.2)[9.5

		(14.8:18.1)]	(10.1:16.9)]	(7.8:12.3)]	(7.2:12.5)]
Total fluoxetine	29[43]	16.6 (15.4:17.9)[17.2 (16.2:18.2)]	11.9 (9.8:14.3)[12.7 (11.0:14.6)]	7.0 (5.3:9.1)[8.7 (7.0:10.8)]	5.3 (3.7:7.5)[7.3 (5.5:9.6)]
Total placebo	32[44]	17.1 (15.6:18.8)[16.9 (15.8:18.1)]	14.2 (12.5:16.2)[13.8 (12.0:15.9)]	8.8 (6.9:11.2)[9.6 (7.9:11.7)]	8.9 (7.1:11.0)[9.9 (8.3:11.8)]
Total 1 session counselling	33[45]	16.9 (15.6:18.3)[17.0 (16.0:18.1)]	13.5 (11.9:15.4)[13.8 (12.4:15.4)]	8.4 (6.6:10.5)[9.5 (7.8:11.4)]	7.4 (5.7:9.5)[8.6 (7.0:10.7)]
Total 6 sessions counselling	28[42]	16.9 (15.4:18.5)[17.0 (15.9:18.2)]	12.6 (10.3:15.3)[12.6 (10.6:15.0)]	7.4 (5.5:9.8)[8.8 (7.0:11.1)]	6.6 (4.6:9.2)[8.4 (6.5:10.9)]

Scores over 9 and over 12 can be used as screening thresholds.

Treatment (drug plus sessions of counselling)	No of patients	Assessment time	
		Baseline	12 Weeks
Fluoxetine:			
Plus 1 session	16[22]	13.3 (11.8 to 15.0)[14.4 (12.8 to 16.2)]	2.9 (1.6 to 4.9)[4.4 (2.4 to 7.4)]
Plus 6 sessions	13[21]	13.2 (11.3 to 15.4)[14.0 (12.1 to 16.1)]	2.8 (1.1 to 5.8)[5.1 (2.6 to 9.2)]
Placebo:			
Plus 1 session	17[23]	14.7 (12.7 to 17.1)[14.0 (12.1 to 16.3)]	7.5 (5.3 to 10.4)[8.1 (6.1 to 10.7)]
Plus 6 sessions	15[21]	13.3 (11.0 to 16.0)[13.8 (11.7 to 16.2)]	3.7 (2.1 to 6.1)[4.9 (3.0 to 8.9)]
Total fluoxetine	29[43]	13.3 (12.2 to 14.5)[14.2 (13.0 to 15.5)]	2.9 (1.8 to 4.3)[4.7 (3.1 to 6.9)]

Total placebo	32[44]	14.0 (12.5 to 15.7)[13.9 (12.5 to 15.4)]	5.4 (3.9 to 7.3)[6.4 (4.9 to 8.4)]
Total 1 session counselling	33[45]	14.0 (12.8 to 15.4)[14.2 (12.9 to 15.6)]	4.8 (3.4 to 6.7)[6.0 (4.4 to 8.1)]
Total 6 sessions counselling	28[42]	13.3 (11.8 to 14.9)[13.9 (12.5 to 15.4)]	3.2 (2.1 to 4.9)[5.0 (3.4 to 7.2)]

Scores of 8-17 indicate mild depression.

When the revised clinical interview schedule was taken as the main outcome measure, the response to fluoxetine was evident within one week. This was also true of the response to six sessions of counselling, even though only one session had been delivered by this stage. Improvement in all four groups was largely complete after four weeks.

Percentage differences in (geometric) mean scores on the revised clinical interview schedule scores were calculated. The difference between fluoxetine and placebo was 37.1% at 4 weeks (95% confidence interval 5.7% to 58.0%) and 40.7% at 12 weeks (10.9% to 60.6%); the difference between six sessions and one session of counselling was 53.9% at 4 weeks (2.3% to 131.2%) and 38.7% at 12 weeks (-9.2% to 111.7%).

The women who received a single counselling session with placebo had smaller changes than all other groups in scores on the revised clinical interview schedule and Hamilton depression scale. However, because of the high variability in the responses over time within each of the study groups, the interaction between drug and counselling treatment was not significant.

An "intention to treat" analysis was also performed, in which last observations were carried forward for dropouts (tables 4 5 6). As table 3) shows, this meant carrying forward baseline scores in most cases. Despite this, the earlier findings were broadly confirmed, although the differences at 12 weeks between women who had received six sessions and one session of counselling were of borderline significance.

Discussion

This study shows the effectiveness of both fluoxetine and cognitive-behavioural counselling in the treatment of women found by community based screening to be depressed 6-8 weeks after childbirth. Combining fluoxetine and six sessions of counselling did not produce additional improvement.

This was not a trial of the effectiveness of counselling itself. All subjects received one session of counselling, and our trial design allowed us to study the additional benefits of an antidepressant

and of further counselling sessions. This design was in part intended to reflect actual clinical practice in primary care. A general practitioner or a health visitor who finds that a woman is depressed postnatally is likely to spend some time listening and advising; this study aimed to show whether it was clinically justified to prescribe an antidepressant as well or provide additional time for further counselling, or both.

An unexpected finding was the great improvement in mood within one week of entering the trial. Cases of "depression" found by community survey are frequently transient and may be more accurately viewed as distress,¹² but there are two reasons for believing that subjects in our trial had true depression. Firstly, the entry criteria (research diagnostic criteria) required subjects to have been depressed for at least two weeks. Secondly, many subjects with symptoms identified by screening were excluded at interview because of insufficient evidence of depressive illness. The improvement after one week was greater in those taking fluoxetine, suggesting that its antidepressant effect begins earlier than is often suggested. The improvement after one week was also greater in those who were going to receive (but had not yet received) further counselling, suggesting that perceived as well as actual support was beneficial.

Because our recruitment began with community screening we were able to assess how closely our subject sample represented depressed postnatal women on a number of demographic and obstetric variables. There was no evidence of any clinically important bias in the sample or in those who completed treatment, although those entering the trial were presumably more accepting of treatment. Our sample therefore represents those women who would be seen by any service that routinely screened for postnatal depression and offered treatment.

These results justify such screening by showing the effectiveness of two forms of treatment. In women who will accept an antidepressant after a single counselling session, further counselling offers no additional benefit. Many will prefer not to take a drug treatment, however,¹⁸ and for them a course of counselling is equivalently effective.

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