Randomised controlled trial of facilitated exercise plus usual care versus usual care only as a treatment for women with a depressive disorder in the first six postnatal months

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Up to 10% of women have a depressive disorder in the first 6 months after birth.[1] Many mothers are not effectively treated, largely due to reluctance to accept medication at this time and limited availability of timely psychological treatment.[1] Physical activity is a potential intervention for postnatal depression (PND). However, evidence is limited to a few small, low-quality studies that suggest facilitated exercise has a modest beneficial effect on the prevention of PND and no statistically or clinically meaningful effect on the treatment of PND.[2]

METHODS OF THE STUDY

This was a randomised controlled trial (RCT) of facilitated exercise (two face-to-face sessions with an exercise facilitator and two support phone calls over 6 months) plus usual care versus usual care only. Women with PND were recruited from primary care if: (1) they were aged 18 years or more; (2) they screened positive for PND on the Edinburgh Postnatal Depression Scale (EPDS) at baseline when responding to a letter of invitation (EPDS score 10+) and 2 weeks later on the telephone (EPDS score 13+); (3) had an ICD-10 diagnosis of major depression or mixed anxiety and depression after 6 weeks but within 6 months of giving birth; (4) were physically inactive (according to UK Department of Health guidelines); (5) did not have psychotic symptoms, alcohol or drug dependence or a further pregnancy. The primary outcome was difference in mean EPDS scores (adjusted for baseline score) between groups at 6 months of follow-up. Of the 9983 invited women, 11% returned the initial screening questionnaire; 100/1150 screened women were eligible and 94 were randomised.

WHAT DOES THIS PAPER ADD

- At 6 months of follow-up, the mean EPDS score was 2.04 points lower (95% CI 4.11 to 0.03, p=0.05) in the active versus control arms; the proportion who 'recovered' (EPDS score 4+ points lower than baseline and total score <13) was 46.5% vs 23.8% (p<0.03). At 12 months of follow-up, there was no statistically significant difference between groups in mean EPDS score or proportion recovered.
- This is the first RCT of a physical activity intervention for the treatment of ICD-10 PND. Compared to care as usual, intervention was associated with a modest reduction in mean depressive symptom scores at 6 months of follow-up, with a twofold higher recovery rate (based on screening instrument scores). However, these differences were no longer statistically significant at 1 year follow-up.
- Participants in the intervention arm reported a similar level of physical activity to the control arm at all times, and marginally higher social support at 6 months (mean score 20.8 vs 18.9, respectively), which was statistically significant at that time point, but the difference was no longer apparent at 12 months (20.8 vs 19.7, p=0.09). Usual care in both arms included antidepressants and psychological interventions. Mechanisms for potential benefit are therefore unclear.

LIMITATIONS

- The response rate to the initial invitations to participate in the study was very low (11% of those approached) and may have been higher among women motivated to engage in the intervention. Therefore, findings may not generalise to all women with PND (among whom low motivation is a common symptom).
- The trial was underpowered and the two-point reduction in the mean EPDS score for the intervention arm is below the four-point difference widely held to be clinically meaningful.[2 3]
- Women with mild, moderate or severe depression were included and the intervention may be more or less effective depending on severity.
- Reported benefits at 6 months were not sustained at 12 months.

WHAT NEXT IN RESEARCH

- Replication in a larger RCT, designed to assess the active ingredient (eg, physical activity, social support, non-specific benefits from increased contact) should be considered using different recruitment methods such as recruitment from children's centres and Improving Access to Psychological Therapies (primary care psychology services) where higher numbers of women with PND are likely to be found and are seeking help.
- A cost-effectiveness analysis which includes a measure of patient satisfaction should also be considered, since exercise may be a more cost-effective intervention with higher patient satisfaction than the commonly used alternatives of antidepressants or guided self-help in the postnatal population.

DO THESE RESULTS CHANGE OUR PRACTICES AND WHY?

No, as there is insufficient evidence at present to recommend wide-scale implementation of exercise-based interventions for PND. This trial used exercise treatment in addition to usual care; therefore, it is important for women not to stop other effective treatments where this intervention is recommended.

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Competing interests None declared.

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REFERENCES

1. **Howard LM**, Molyneaux E, Dennis CL, *et al*. Non-psychotic mental disorders in the perinatal period. *Lancet* 2014;**384**:1775–88.
2. **NICE.** *Antenatal and postnatal mental health: clinical management and service guidance*. London: NICE, 2014.
3. **Matthey S.** Calculating clinically significant change in postnatal depression studies using the Edinburgh Postnatal Depression Scale. *J Affect Disord* 2004;**78**:269–72.