INAHTA Briefs

Issue 2010/125

Title **Psychological Interventions for Postnatal Depression – Randomized Controlled Trial and Economic Evaluation (The Ponder Trial)**

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Reference Volume 13.30, ISSN 1366-5278. www.hta.ac.uk/project/1336.asp

Aim

Primary Aim - To estimate differences in outcomes (for postnatal women, infants, and family) attributed to training health visitors (HVs) in identifying depressive symptoms and delivering a psychological intervention based on either cognitive-behavioral principles or person-centered principles in primary care at the individual level for women at risk of postnatal depression (PND). *Secondary Aim* - To establish the relative cost effectiveness of the intervention from the NHS perspective, relative to usual care (control). *Cluster level objective* - To provide intervention cluster HVs with skills to identify depressive symptoms and provide effective psychological intervention. *Individual level objectives* - To identify:

1. Women at risk of PND by the presence of depressive symptoms at 6 weeks postnatally, using the Edinburgh Postnatal Depression Scale (EPDS).
2. Women eligible (identified by two EPDS scores ≥12.) for 8 psychological intervention sessions, 1 hour per week.
3. Differences in costs for use of services in the intervention group vs control.

Secondary objectives - To: 1) Monitor change in women's health at 6, 12, and 18 months postnatally; 2) Use the Schedule for Clinical Assessment in Neuropsychiatry (SCAN) to assess the baseline severity of depression; 3) Examine outcomes in women's partners to 18 months; 4) Measure infant development at 18 months; and 5) Follow-up the cohort of all women who consented to take part in the study.

Conclusions and results

Of 418 at-risk women with a 6-week and 6-month EPDS score, 45.6% (67/147) in the control group vs 33.9% (93/271) in the intervention group had a 6-month EPDS score ≥12. The absolute difference of 11.7% (95% CI 0.4-22.9) was statistically significant (p=0.028 adjusted for covariates). The mean EPDS score (secondary outcome) was 11.3 (SD 5.8) for control group women and 9.2 (SD 5.4) for intervention group women. The mean difference was -2.1 (95% CI -3.4 to -0.8). This difference (p=0.002) remained statistically significant after adjusting for 6-week variables (p=0.001). There was also a significant difference in the SF-12 MCS, the SF-6D, the CORE-OM Total score, the STAI, and PSI, all favoring the intervention group. For all 2659 women followed up at 6 months postnatally, 11.7% intervention group women vs 16.4% control group women had an EPDS score ≥12 at 6 months (p=0.004). The mean EPDS score was 6.4 (SD 5.2) in the control group and 5.5 (SD 4.7) in the intervention group (p=0.001).

Recommendations

The statistically significant difference between the proportion of intervention group and control group at-risk women with a 6-month EPDS score ≥12 indicated that the improvement was probably attributable to the HV training intervention. The effect on the primary outcome arose despite the small number of psychological intervention sessions accepted. The 95% CI for the observed 11.7% difference was 0.4-22.9%. The true treatment effect may be less clinically important than a 15% difference. The economic evaluation found that the HV intervention was cost effective over the HV usual care.

Methods

See Executive Summary link at www.hta.ac.uk/project/1336.asp.

Further research/reviews required

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ISSN 1654-501X