

Psychological interventions for postnatal depression: cluster randomised trial and economic evaluation. The PoNDER trial

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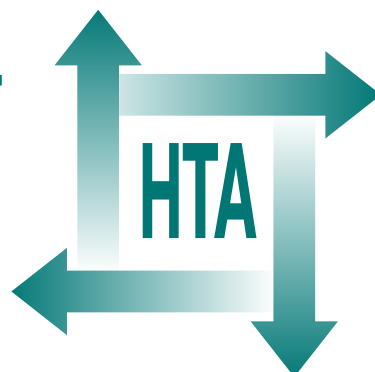
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Executive summary

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Executive summary

Background

About 12.9% of women may have depression during the first postnatal year. There are problems in the identification of postnatal depression (PND) and the Edinburgh Postnatal Depression Scale (EPDS) has been used in the UK, with a clinical interview, to help assess postnatal women's mood and identify depressive symptoms and suicidal thoughts.

In the short term PND has been found to be amenable to treatment but not prevention. Antidepressants are effective but compliance is not good and it is not known which class is most helpful. Psychologically informed interventions offer a practical alternative and the potential role for health visitors (HVs) in PND has been promoted. The trial aimed to build upon evidence and address the limitations of previous research in PND and to examine the role of HVs in this context.

Aim and objectives

The primary trial aim was to estimate any differences in outcomes for postnatal women, families and infants attributed to special training for HVs in the intervention groups (IGs), delivered at GP practice (cluster) level, in systematically identifying depressive symptoms and delivering psychologically informed sessions, based on either cognitive behavioural principles or person-centred principles in primary care, compared with the HV usual care control group (CG). The secondary aim was to establish the relative cost-effectiveness of the intervention from an NHS perspective, relative to control.

The cluster level objective was to prepare the HVs to provide the individual level intervention, which was clustered within the wider training for the cluster-level intervention. The individual level objectives were to:

- identify at-risk women with a 6-week EPDS score ≥ 12

- identify IG at-risk women with an 8-week EPDS score ≥ 12 eligible for the HV psychological sessions
- identify any differences in the proportion of IG and CG at-risk women with a 6-month EPDS score ≥ 12 at 6 months postnatally
- monitor differences in secondary outcomes at 6, 12 and 18 months postnatally
- identify any differences in costs for use of services
- examine outcomes for women's infants and partners to 18 months postnatally.

A further set of secondary study objectives for all women who consented to take part in the study were to:

- identify any differences by group in the proportion of all women with a 6-month EPDS score ≥ 12
- monitor differences by group in secondary outcomes in all women at 6, 12 and 18 months postnatally
- monitor differences by group in the health of all women's partners at 6, 12 and 18 months postnatally
- monitor differences by group in infant development for all women to 18 months postnatally
- identify any differences in costs for use of services for all women in the intervention versus control groups.

Methods

The study was a pragmatic randomised cluster trial with clusters allocated to experimental HV training arms or control. This pragmatic trial of the effectiveness of an intervention provided under normal conditions aimed to answer a clinical question in a real-life clinical situation, excluding as few women as possible.

Eligible consenting women were sent a postal questionnaire at 6 weeks postnatally. All women with a 6-week EPDS score ≥ 12 were at-risk women and were included in the main trial of the two approaches, the cognitive behavioural approach

(CBA) or the person-centred approach (PCA), compared with control. The IG at-risk women with a 6-week EPDS score ≥ 12 were interviewed using the Schedule for Clinical Assessment in Neuropsychiatry (SCAN). Women classified as moderately or severely depressed were asked to state their preference for the psychological sessions or a selective serotonin reuptake inhibitor (SSRI), or both.

The IG at-risk women were reassessed at 8 weeks postnatally by a face-to-face HV administration of the EPDS. At-risk women with an 8-week EPDS score ≥ 12 were eligible for psychological sessions.

The cluster level intervention therefore comprised the package of HV training in the assessment of postnatal women, combined with providing either the CBA or the PCA sessions for women eligible for them, according to the HV's management protocol, plus the option of a SSRI if indicated.

All women in the three main arms of the study, the CBA IG, the PCA IG and the CG, were followed up at 6, 12 and 18 months postnatally by postal questionnaires. The primary outcome was the proportion of at-risk women with a 6-month EPDS score ≥ 12 .

The primary comparison was between those at-risk women in the combined clusters randomised to HV training and those women in practices randomised to provide HV usual care (control) to identify any differences attributable to providing the HV training. The secondary comparison was to determine any differences between the proportion of women with a 6-month EPDS score ≥ 12 in the two main psychological approach groups (CBA and PCA) to identify any differences attributable to training in one or other of the two approaches.

Results

Health visitors in 101 clusters in 29 primary care trusts collaborated in the 3-year study. From 7649 eligible women 4084 (53.4%) consented to take part: 17.3% (595/3449) of women who returned a 6-week questionnaire had a 6-week EPDS score ≥ 12 and were at-risk women; 70.3% (418/595) of at-risk women had a 6-month EPDS score available. In total, 45.6% (67/147) of CG at-risk women had a 6-month EPDS score ≥ 12 versus 33.9% (93/271) of IG women. The absolute difference of 11.7% (95% CI 0.4 to 22.9%) was statistically significant ($p = 0.036$). This difference suggests that the odds

of an IG woman having a 6-month EPDS score ≥ 12 was 0.62 (95% CI 0.40 to 0.97) times the odds for a CG woman. After adjusting for covariates, the odds ratio for the IG effect was relatively unchanged at 0.60 (95% CI 0.38 to 0.95) and this effect remained statistically significant ($p = 0.028$).

A total of 32.9% (46/140) of at-risk women in the CBA group versus 35.1% (46/131) in the PCA group had a 6-month EPDS score ≥ 12 (difference 2.2%, 95% CI -14.2% to 10.1%, $p = 0.74$). This difference suggests that the odds of a PCA group woman having a 6-month EPDS score ≥ 12 is 1.09 (95% CI 0.64 to 1.88) times the odds for a CBA group woman. After adjusting for covariates, the odds ratio for the PCA versus CBA group was 1.00 (95% CI 0.57 to 1.77) and this effect was not statistically significant ($p = 0.99$).

Secondary outcomes included the mean EPDS score at 6 months. The CG mean 6-month EPDS score for at-risk women was 11.3 (SD 5.8) versus 9.2 (SD 5.4) for the IG. The mean difference, -2.1 (95% CI -3.4 to -0.8) ($p = 0.002$), remained statistically significant after adjusting for 6-week variables ($p = 0.001$). There was also a significant difference in the Short-Form 12 Health Status Questionnaire (SF-12) mental component summary, SF-6D, Clinical Outcomes in Routine Evaluation (CORE-OM) total score, State-Trait Anxiety Inventory (STAI) and Parenting Stress Index (PSI), all favouring the IG.

The pre-trial sample size calculation was based on detecting an absolute difference of 15% (approximately equivalent to an odds ratio of 0.54) in the proportions of at-risk women with a 6-month EPDS score ≥ 12 [i.e. a minimum clinically important difference (MCID) of 15%]. We observed a smaller absolute difference, 11.7%, than our anticipated MCID. The 95% confidence interval suggests that the true treatment difference lies between 0.4% and 23%. So it is consistent with the data that the true treatment effect, although statistically significant, may be small and potentially not very clinically important. Therefore we are unable to confirm or exclude our a priori clinically important effect of 15%.

In total, 16.4% (150/914) of all women in the CG had a 6-month EPDS score ≥ 12 compared with 11.7% (205/1745) in the IG ($p = 0.003$). The absolute difference was 4.7% (95% CI 0.7 to 8.6). The CG mean 6-month EPDS score for all women was 6.4 (SD 5.2) compared with 5.5 (SD 4.7) for the IG ($p < 0.001$). Most of the mean scores for the

secondary outcomes for all women were statistically significant, favouring the IG.

The economic analysis results showed a consistent pattern of psychological approaches being cost-effective at funding levels used by the National Institute for Health and Clinical Excellence. This effect was produced by lower mean costs and higher mean quality-adjusted life-years gained in the IGs. Although these aggregate differences were not statistically significant in isolation, in combination they produce a high probability of the intervention being good value for money. The findings were consistent across both the at-risk women and all women cohorts at the 6-month and 12-month follow-ups. The CBA appeared to be the most cost-effective across all analyses.

Conclusions

The package of HV training was effective compared with HV usual care in reducing the proportion of at-risk women with a 6-month EPDS score ≥ 12 , with a wide confidence interval for the estimated intervention effect, suggesting that the true treatment effect may be small. The effect remained for 1 year. The economic evaluation found that the HV intervention was highly likely to be cost-effective compared with the control. We found no difference between the CBA and the PCA.

Recommendations for further research

Further research should:

- explore ways to improve the accurate detection by HVs of symptoms of mental health problems experienced among postnatal women
- identify ways to improve the effectiveness of HVs' therapeutic relationships with postnatal women
- investigate the unexpected non-specific effect of the HV intervention on all women as randomised
- adopt a Bayesian approach in economic analyses and look at longer term costs within a modelling framework.

Trial registration

This trial is registered as ISRCTN92195776.

Publication

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 99/33/51. The contractual start date was in April 2003. The draft report began editorial review in August 2006 and was accepted for publication in October 2008. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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