



Title A Pragmatic Randomized Controlled Trial to Compare Antidepressants

With a Community-Based Psychosocial Intervention for the Treatment

of Women With Postnatal Depression: The RESPOND Trial

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## Aim

To: 1) evaluate clinical effectiveness at 4 weeks of antidepressant therapy compared to general supportive care for mothers with postnatal depression (PND); 2) compare outcomes at 18 weeks of those randomized to antidepressant therapy with those randomized to listening visits as the first intervention (both groups were to be allowed to receive the alternative intervention after 4 weeks if the woman or her doctor so decided); and 3) assess acceptability of antidepressants and listening visits to users and health professionals.

# Results and conclusions

At 4 weeks, women were more than twice as likely to have improved if they had been randomized to antidepressants compared to listening visits, which started after the 4-week follow-up, ie, after 4 weeks of general supportive care (primary intention-to-treat [ITT], 45% versus 20%; odds ratio [OR] 3.4, 95% confidence interval [CI] 1.8 to 6.5, p < 0.001). Explanatory analyses emphasized these findings. At 18 weeks, ITT analysis revealed that the proportion of women improving was 11% greater in the antidepressant group, but logistic regression analysis showed no benefit for one group over the other (62% versus 51%, OR 1.5 [95% CI 0.8 to 2.6], p = 0.19). Overall, there was a difference between the groups in favor of the antidepressant group of about 25 percentage points at 4 weeks, which reduced at 18 weeks. No statistical support existed for a benefit of antidepressants at 18 weeks, but 95% CIs could not rule out a clinically important benefit. Trial design meant that by 18 weeks many of the women initially randomized to listening visits were also receiving antidepressants, and more vice versa. The lack of evidence for differences at 18 weeks is likely to reflect a combination of reduced power and the considerable degree of switching across the two interventions. Qualitative interviews with women revealed a preference for listening visits, but an acceptance that antidepressants might be necessary. Women found both antidepressants and listening visits effective depending on their circumstances and preferences. They wished

to be reassured that their GP and health visitor (HV) were offering continuity of care focusing on their particular set of circumstances. Interviews with GPs and HVs revealed a lack of collaboration in managing care for women with PND; neither professional group was willing to assume responsibility. The trial indicates that early treatment with antidepressants leads to clinical benefit for women with PND.

#### Recommendations

This study has shown that at 4 weeks, antidepressants were significantly superior to general supportive care. The data also confirm that a substantial number of women suffer from depression in the 6-month postnatal period. There is an urgent need for GPs and HVs to agree on care pathways for these women. Starting women on antidepressants early in the illness is likely to result in the fastest resolution of symptoms, which will require GPs and HVs to accept responsibility for making the diagnosis and agreeing on management for individual women. The need to ensure adequate services for PND is heightened by the potential for long-term adverse consequences for the women and their children.

## Methods

See Executive Summary link www.hta.ac.uk/project/1373.asp.

#### Further research/reviews required

See Executive Summary link www.hta.ac.uk/project/1373.asp.