RESPOND

Professor D. Sharp
Academic Unit of Primary Care
University of Bristol
Cotham House
Cotham Hill
Bristol BS6

(0117) xxxxxxx

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Patient Information Sheet B (i)

Antidepressant drug therapy vs a community based psychosocial intervention for the treatment of moderate postnatal depression: a pragmatic randomised controlled trial
RESPOND
ISRCTN 16479417

Thank you for helping us with the first part of this study and completing the EPDS forms. As discussed on the phone your EPDS score showed that you might be experiencing symptoms of postnatal depression so we have arranged for our research associate, Laura Bridges, to come and visit you at home on

Date: at Time:

If you are unable to make this appointment, please could you call the RESPOND team on 0117 xxxxxxx or 07795 xxxxxx to arrange a more convenient time for her to visit?

What happens now?
If an updated EPDS at the home visit and your answers to the further questions show you are experiencing symptoms of postnatal depression, we would like you to participate in our study comparing antidepressants and counselling from a Health Visitor in the treatment of postnatal depression. Antidepressants and Health Visitor counselling are both accepted treatments for postnatal depression. This study aims to increase our understanding of under what circumstances and for which women these two treatments are most effective.

The study design allows everyone to try both treatments – antidepressants and counselling. However, the order in which women receive the treatments will differ. We will randomise women, effectively like tossing a coin, to see which treatment is offered first. If after a

certain time you do not respond to that treatment, you will be offered the alternative treatment.

The type of antidepressant will be agreed between you and your doctor. He or she will follow you up at monthly intervals whilst you are taking the tablets.

The counselling will begin four weeks after seeing the Research Associate and comprise a course of 4 to 8 sessions from a special Health Visitor who will come to your home. She will help you talk about your difficulties and look at ways of overcoming them. Whilst in the study, your GP will be able to offer additional treatment as s/he thinks fit.

We will ask you to complete self-report questionnaires 4, 18 and 44 weeks after entering the study. At about the time of your baby's first birthday, we would like to visit you at home to see how you are feeling and do a brief developmental assessment of your baby. The assessment of the baby will be looking at how they are progressing in terms of sitting up, crawling, holding and playing with small objects, starting to talk, etc.

The questionnaires will focus on how you are feeling, how you are coping at home and looking after your family, and your relationship with the baby and your partner. They will take about 30-40 minutes to complete.

Having a baby also has an impact on your partner and their views on how you are feeling are also important. We hope that you will allow us to contact your partner so they can fill in some very similar questionnaires, at the same time points.

We would need to look at the GP records for you and your baby to count up the number of consultations, referrals and prescriptions you and he/she have had since the baby was born.

[1]Finally, we will ask you to agree to possibly being approached by our Research Associate to be interviewed so we may hear your views on the treatment of postnatal depression.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a further consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you do not wish to take part we will suggest that you consult your GP to see if you need treatment.

What about antidepressants and breastfeeding?
The evidence shows that the amount of antidepressants that get into breast milk and into the baby is so low it is unlikely to do any harm. Babies who have been in the womb or been breastfed, while their mothers have been on antidepressants, have had no serious problems reported. However, we recognise that this might be an area of concern. If you are breastfeeding, your GP will talk to you about any advantages and disadvantages of antidepressants in this situation, and which antidepressant would be the best one to take. You can then decide about participating in the study where you have a 50:50 chance of being offered an antidepressant as the first treatment.

What are the side-effects of the antidepressants?
The choice of antidepressant will be made by your GP in consultation with you and s/he will explain any possible side-effects. You will also be given a leaflet explaining the possible side-effects. The antidepressants, known as selective serontonin re-uptake inhibitors (SSRIs), are generally well tolerated, but you can have side-effects in the first couple of weeks, e.g. feeling sick/nauseated, and sometimes feeling more on edge or anxious and sexual side effects. Usually these are mild and settle down, but if you are concerned in any way, you should consult your GP.

Confidentiality
All the information collected will be stored securely according to the Data Protection Act. We will not release any identifiable information to any other organisation. No-one will be able to identify any of the participants from the published findings. Once the study has been completed our record of your name and address will be destroyed.

Will taking part in the study affect my treatment?
If you agree to take part in this study, the routine care you receive from your general practice will not change in any way at all. Your GP will retain full clinical responsibility for your care. As usual, you will be able to consult with your GP at any time you wish.

Further questions
If there is any further information that you require, please contact the RESPOND Team at the telephone number 0117 xxxxxxx or contact the study lead researcher Professor Debbie Sharp at Bristol at the telephone number (0117) xxx-xxxx

Thank you for considering helping us with this study.

Yours sincerely

Professor D. Sharp