



OPT Study

Oxford Postnatal Treatment Study



Contact Information
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Participant Information Sheet

*You are being invited to take part in a research study
and it is up to you whether you want to take part...*

Why have I been invited to take part in this study?

We are contacting you because your GP or other healthcare professional felt that you might be interested in a research study we are carrying out. In this study we are providing therapy for mothers who have been feeling low or depressed recently and have a young baby of 4 ½ - 9 months. Before you decide whether you would like to take part, it is important that you know why we are carrying out the study and what it will involve. If you have any questions or concerns at all, you are welcome to discuss them with one of our research team. You might also want to discuss taking part with your partner, family, GP or health visitor.

What is the research for?

In this study, we are looking at how best to help mothers who are depressed. We know that one therapy for depression, Cognitive Behaviour Therapy (CBT), has been shown to help people deal with their negative thoughts and feelings. We would like to see if providing CBT together with a further treatment (as a combination) may be even more helpful for mothers in the postnatal period.

What should I do if I would like to take part in this study?

This information leaflet came to you with an invitation letter from your own GP or health care professional. Once you have read this information sheet, if you feel you might like to take part, you should fill in the enclosed questionnaire and reply slip and return it in the freepost envelope. Alternatively, you could telephone our research coordinator, Elena Netsi, or send her a text message or email her. All of these contact details are in bold at the top of this information sheet.

What happens when I have sent in my forms?

Once the research team receives your forms, they will contact you by telephone and will answer any questions you might have. This will also give us a chance to check that the study would be workable for you (e.g. that you are not moving away within the next few months). At this point, if it is felt that this therapy might be helpful for you, a researcher will arrange to come and see you for the first visit in your home, at a time that is convenient for both you and your baby. If it seems though, that this therapy might not be suitable for you, we will discuss with you alternative ways of getting help should you wish it, and also offer you a leaflet with a list of other sources of help that you might find useful.

What does the study involve and how long does it last?

One of our therapists will visit you in your home on 11 occasions over a period of 18 weeks, with a further two therapy sessions when your baby is around 18 months old. In addition, one of our assessors will visit you before therapy begins and then again when

your baby is 12 months and 2 years old. At this time you will also be invited to visit us once in our research office in Headington. Every visit (assessment and therapy) will last approximately 1½ hours. You would receive £20 at the end of the each assessment visit (four in total, making a total of £80). This money is a token of our appreciation, and in recognition that you have given up time for the assessments in our study.

What will I have to do?

You are asked to take part in the assessment and therapy sessions. There will be questionnaires and interviews at the assessment visits. The interviews will be mainly about how you have been feeling and to see how things have been for you. We would also like to film you and your baby at the assessment visits. All visits would be arranged at a time convenient for you.

When your child is 2 years old, there will be some developmental assessments of your child. One of these would take place in our office in Headington. (One of the team could come and collect you and your child, and bring you home again afterwards. If you decide to make your own way to us travel expenses will be reimbursed).

The table below gives an outline of what is involved and at what timepoints.

Name of Session	Baby's Age (approximately)
First assessment	6 months
Your therapy (11 visits)	6 - 10 months
Second assessment	1 year
Two additional therapy sessions	16 -20 months
Final assessments (2 visits)	2 years

What happens at the first assessment?

At this session the researcher will explain the study to you in detail and give you the chance to ask questions about it. If you are happy to take part, you will be asked to sign a consent form. There will be questions about you and your baby, and an interview with the researcher about how you have been feeling, both now and at other times in your life. You will be asked to fill in some questionnaires, and at the end of the visit the researcher will film you and your baby playing for a short while with toys that we will bring along.

Part of the aim of this initial assessment session is to check that all of the study criteria are met. After this visit, a therapist will be in touch to arrange to visit you in your home for the first therapy session.

What kind of therapy will I receive in the eleven therapy sessions?

You will receive Cognitive Behaviour Therapy (CBT), which we know is an effective treatment for depression. In addition, you will receive one of two other forms of therapy: either relaxation therapy to help reduce stress; or support for mother-baby communication. The different therapies are explained below.

Sometimes we don't know which way of treating people is best and what combination of treatments will help them most. To find out, we offer people different combinations of treatments and compare them. So, for this study, each mother will receive either CBT plus the relaxation therapy, or CBT plus the support for mother-baby communication, with allocation made by chance (i.e., randomly, so each mother will

have a 50% chance of receiving one or other of these two combinations). You will know at the beginning of treatment which combination you will receive.

What is Cognitive Behaviour Therapy? (CBT)

This therapy is one that is recommended for depression within the NHS, and is known to be effective. You may have heard about it already, or know someone who has experienced it, or your GP may have mentioned it to you. It is a popular therapy and its effects are likely to be long-lasting. Basically, CBT is based on the idea that the way you feel is affected by your thoughts and beliefs, and what you do. Having a baby is a major event and can be tiring and stressful, and it is a common time for women to become low or depressed. CBT aims to help people stand back and examine their thoughts and beliefs and to explore alternative ways of thinking, making decisions, and coping with everyday life. These sessions will give you the opportunity to talk about your thoughts and feelings, and to help you develop new skills to improve how you feel.

(For more information about CBT and what it involves, the Royal College of Psychiatrists produce a leaflet. It is available for free online at: <http://www.rcpsych.ac.uk/mentalhealthinfoforall/treatments/cbt.aspx> or if you do not have access to the internet, please telephone us and we can send you a copy of the leaflet in the post.)

What is the Relaxation Therapy?

Relaxation therapy aims to help people reduce levels of tension and to give them a way of helping to deal with the everyday stresses they face. Bringing up a baby in any circumstance can be stressful, and especially so if you are depressed. Relaxation therapy is designed to help you to identify certain muscle groups that may be tight and tense, and will teach you how to relax them. There is a series of simple exercises to do that the therapist will demonstrate in the sessions. Relaxation therapy aims to provide a skill for you to release tension easily.

What is the support for Watch & Discover (mother-baby communication)?

This approach looks at how your baby explores the world around him/her and communicates with you. Life with a new baby can be so busy and demanding, and this support allows you to take time to sit back, unpressured, to tune into your baby and perhaps see him/her in a way you've not had the time to do so far. This support involves making short films with your baby, sometimes playing with toys, at other times doing everyday things, when we try to capture ordinary examples of life with your baby. During the sessions with the therapist you will be able to look at these videos together and discuss them.

What happens at the 1 year and 2 year assessments?

When your baby is 1 year old and when he/she is 2 years old, one of our assessors will visit you at home to find out how you are feeling and film your baby's play. At 1 year, we will ask you if it is ok for us to use audio-visual (video) material that we have of you and your child in teaching and research presentations. This is entirely up to you and if you would rather we didn't use it outside of the study this is fine and there would be no change to the care you receive or your involvement in the study. At 2 years there will also be a visit to our offices in Headington to carry out some standard child developmental assessments (the assessor can come and fetch you if this is what you prefer; but if you decide to come in under your own steam, we will reimburse you for your travel expenses).

Do I have to take part and what will happen if I don't want to carry on with the study?

You do not have to take part in this study and if you decide not to take part, this will not affect any healthcare you or your child/ren receive. If you decide you would like to take part, but change your mind later, you can withdraw from the study at any time. If you

begin the course of therapy sessions and then decide to stop, you may be asked if it would be possible to keep in contact with us to let us know how you are doing. If you withdraw from the study, we would only keep any data we have collected from you with your continued and explicit permission.

What happens after the study finishes?

The study is for a set time period and will finish when your child reaches the age of two. Once the study finishes, if you feel you would like further help, although we would not be able to provide you with therapy ourselves, we would be happy to discuss alternatives with your GP, and also provide you with some helpful information.

What will happen to my information and will it be kept confidential?

If you take part in the study, we will write to your GP to let him/her know. All the information we collect will be regarded as strictly confidential. We will give you a unique participant number so that your name and address are not stored with any other confidential information that you give us. All the data, including audio-visual material will be kept in a secure place, separate from any other identifying details. Responsible members of the University of Oxford or the relevant NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations. They will of course keep this data entirely confidential. Copies of video material be given to you for you to keep after your last visit (when your child is approximately 2 years old). Copies of the audio-visual material will be kept securely and confidentially by the University of Oxford until your child reaches the age of 21. This is in case your child would like to look at the material when they are older and is in accordance with Standard Operating Procedures of research studies of this type.

How many people are taking part in the study?

We plan to see up to 150 mothers over a total study period of several years.

Will I find out the results?

Everyone will be sent a short report about the study after the results have been analysed. We will give you the details of a website where you can access more information.

How is this study funded?

The study is funded by the Wellcome Trust, a large medical research charity in the UK. You can find more information about the funder on their website at www.wellcome.ac.uk.

Who will I contact about my health issues when I am in the study?

Throughout the study, your on-going medical care will be the responsibility of your GP. We will ask you about any medication you are using, but we will not ask you to stop taking any medicines your GP has prescribed. If your mood suddenly deteriorates, you can contact the therapist or your GP. If there is an urgent problem, you should contact your GP.

What are the possible benefits of taking part?

CBT, which all participants will receive, is the treatment recommended by the NHS for people with depression. CBT can help you to make changes to the areas of your life that you are not happy with at the moment and may help you to feel better. Relaxation therapy has been shown to be an effective method of helping people to reduce tension, and is a skill that can be used at any time. The support for mother-baby communication has been used in several research studies with mothers and babies, and in general they have enjoyed it and found it to be helpful.

What are the possible disadvantages of taking part?

You will need to put aside about an hour and a half for each therapy and assessment session. You may find some of the things we discuss with you upsetting. If during the sessions you were to feel uncomfortable or distressed for any reason, we would of course stop the session, and only carry on once you are happy to do so.

What if there is a problem?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of the study, you can either contact our research team directly, or contact the Head of the University of Oxford Clinical Trials and Research Governance office on 01865 743005 or by email heather.house@admin.ox.ac.uk. Given the nature of this study, it is highly unlikely that you will suffer harm by taking part. However, the University has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect participant safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Berkshire Research Ethics Committee (ref: 10/H0505/55).

What happens next?

If you would like to take part, please phone or email us, or return the reply slip in the freepost envelope provided. One of the OPT Team's researchers will then call you to discuss the study and answer any questions you may have.

OPT Study Research Directors:	Professor Alan Stein alan.stein@psych.ox.ac.uk 01865 223911	Professor Lynne Murray lynne.murray@rdg.ac.uk 0118 3786302	Professor Peter Cooper p.j.cooper@rdg.ac.uk 0118 3786617
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