



Child & Adolescent Mental Health Service

Lennard Lodge 3 Lennard Road CROYDON CRO 2UL

Tel: 020 8700 8800 Fax: 020 8700 8843

Patient Information Sheet and Consent Form

The Lennard Lodge Outcome Study and trial of standardized assessment ICRCTN31394658

You are being invited to participate in a research study because your child has been accepted on to the waiting list to attend Lennard Lodge. This study will be conducted by the Lennard Lodge Outcome Research Team, led by Tamsin Ford, Lennard Lodge, 3 Lennard Road, Croydon CR0 2UL. Before you decide to participate, it is important that you understand why the research is being done and what it will involve. Please take the time to read this information carefully and if you wish, discuss it with your GP, friends or family.

What is the purpose of the study?

This study is being carried out because we are investigating what happens to children treated at Lennard Lodge in terms of their problems, the impact on their life, and contact with other professionals. The purpose of this study is to measure how coming to Lennard Lodge reduces your child's difficulties at home and at school and which types of treatments work the best. We will also be seeing if a method of estimating how much your child has changed compared to children with similar problems who have not received any treatment works.

We are also studying whether collecting additional information prior to your first appointment makes it easier for the therapist to understand and help your child. Gathering this information will take up your time, but may help the clinic direct your child to the therapist and intervention best able to help their difficulties, reducing time on waiting lists or the number of appointments. However, we cannot be certain about this until we compare what happens to a group of children with this information to a group without it.

Why have I been chosen?

About 500 parents of the children accepted on to the waiting list of Croydon CAMHS are taking part in the study. You have been chosen to take part because of your child was accepted on to the waiting list.

Do I have to take part?

Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. If you do decide to take part, you are free to leave the study at any time without giving a reason. This will not affect your child's future care in any way.

What will happen to me if I take part?

- You will be asked questions about your child's difficulties, your family situation and how your child is doing at school. This will take about sixty minutes. You will be put into one of two groups at random (like the toss of a coin) to decide whether this information about your child's emotions and behaviour will be given to their therapist before you meet them or not. You have a 50% chance of them having access to it. You can provide this information at an interview with one of our researchers, at the clinic or at home. Alternatively, you may complete it yourself on a computer, either in the clinic or elsewhere via the internet.
- You will also be asked to fill in brief forms about how your child is doing and how satisfied you were with the service 6 months after they were first seen by the clinic. You might be asked to complete some or all of these forms anyway, even if you were not part of the study.
- You will be asked to fill in the same brief form about your child's emotions and behaviours, and any services you have contacted every six months until the end of the study even if your child no longer goes to the clinic. The study will end in up to two and half years, depending on when you join.
- Your child's therapist will also be asked to complete questionnaires on how your child is doing at six months after you were first seen and at six monthly intervals after that.
- If you agree we would like your child's teacher to fill in a form about your child's behaviour and emotions at school and any difficulties in learning at the beginning of the study.
- If you agree, we would like to keep in touch so that we can contact you in the future to see how your child is doing.
- Being in the study will not change the treatment that your child receives, other than having a 50% chance that the therapist had the extra information you gave before meeting you.

What is the additional information that is being tested?

The additional information that we think might help your therapist to understand your child better is called the Development and Well-Being Assessment. It will ask you about your child's emotions and behaviours, and a shorter version will be posted to your child's teacher, if you agree. Information from this assessment will be passed to your child's therapist in a random half of the children in the study, but we need it on all children in the study. More information about the assessment can be found at www.dawba.com or you can contact Tamsin Ford at 020 7848 0466.

What are the possible disadvantages and risks of taking part?

You will need about sixty minutes completing the initial assessment, but this initial assessment may not be passed on to your therapist. The follow up questionnaires will take 10-15 minutes to complete. We will be able to pay you £15 towards your time and travel expenses at the end of the study.

USER INVOLVEMENT: As a service we wish to obtain your views about our service and would like to involve users in future developments.

What are the possible benefits of taking part?

Your child's therapist may receive extra information that may help them understand your child better. The study aims to improve CAMHS services for your child and others.

Will my taking part in this study be confidential?

The doctor conducting the study or the people working with the doctor will collect information about you and will enter these data, without your name, on a case report form, which has a patient identification number. All these data collected about you and from you during the course of the research will be kept confidentially in a locked research office. The data collected will be used without your name for the research, but we will need to keep your name on a database in order to keep in touch. Your name will not appear in any study reports or publications and no one outside the research team will have access to this data.

In addition, in order to verify the correctness of these data, it may be necessary to directly compare them with your medical records. Any person checking your medical notes will be required to keep these data confidential and will have to sign an agreement to do so.

You have an access right to data and can ask for data to be reviewed as appropriate according to local law and procedures. You can discuss this issue further with your therapist.

What will happen to the results of the research study?

Results from the study may be published in medical journals, without the use of any information that could identify you or your child. The results will also be used to inform us on the best treatment for children with emotional and behavioural problems.

Who is organising and funding the research?

The study is being funded by the Medical Research Council who fund a large amount of clinical research in the UK.

Who has reviewed the study?

The ethical committee for South London and Maudsley NHS Trust / Institute of Psychiatry, Kings College London.

Contact for further information:

If you or your relative(s) have any questions regarding the study or in the case of study related injuries you may contact Tamsin Ford at 020 7848 0466. You will receive a copy of the information leaflet and consent form to keep.

Agreement to take part in the project

Title of Project: The Croydon CAMHS Outcomes Study

Ethics Approval Number: 150/05

Name of Research Coordinator: Tamsin Ford

I confirm that I have read and understand the information sheet dated 25 may 2005 for the above study and I have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without explanation, and without my medical care or legal rights being affected.

I have been given a full explanation of the purpose of the study, of the procedures involved and what I am expected to do. The research worker has explained the possible problems that may arise as a result of me taking part in this study. I have had time to ask questions and I have received satisfactory answers.

I understand that sections of any medical notes may be looked at by responsible individuals from the study team where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

I confirm that I do not wish to restrict the use of personal data or results which arise from this study in any way, except where this conflicts with my rights under the data protection laws.

I agree the research team keeping in contact so that I could be invited to join any follow up study YES NO (please delete as applicable)

I DO / DO NOT (delete as applicable) grant my consent for the research team sending the Development And Well-Reing Assessment guestionnaire about my

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teacher.			J	•		
Child's r	name					

School

Best teacher to contact

Name of Parent Date Signature

Name of person taking consent Signature Date (if different from Research Coordinator)

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For further information please feel free to contact Robert Gregory, on 020 8700 8877

1 copy for patient, and 1 for Research Coordinator.
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