Information sheet

**A close up of a sign

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**A Study of Mood and**

**Wellbeing in Families**

**Information sheet about the research**

**Please keep this copy**

**Parent**

# A study of mood and wellbeing in families

You are being invited to take part in a research study. Before you decide whether to take part in this research, it is important that you understand why the research is being carried out and what it will involve. Please take as much time as you need to read this information carefully and discuss it with others if you wish. You are welcome to contact us if there is anything that is not clear to you, or if you would like further information. You may take as much time as you need to decide whether or not you would like to take part.

**What is the purpose of the study?**

Everyone experiences low mood from time to time. Occasionally, this low mood becomes persistent and interferes with home and work life. This is what we call depression. Depression is one of the most common health problems in the world and affects 350 million people worldwide. Many people’s lives would be improved if we could find out how to reduce the number of people affected by this condition. In order to develop more effective ways of treating depression and stop it developing in the first place, it is really important to understand how mood problems begin. To do this, long-term studies that track people’s mood and wellbeing over time are essential. This is the sort of study that, with your help, we aim to carry out.

We know that depression can sometimes run in families, but that it can also develop for reasons such as having financial difficulties or experiencing stressful events. In our earlier study that you took part in, we identified a number of factors that protect young people from developing low mood. We have also found a number of factors that increase the possibility of developing depression. Importantly we found that even when individuals do have some risk factors, they do not necessarily develop problems with low mood. Our aim in this study is to follow-up those research leads and to examine mood and well-being at the transition to adult life. In this next phase of the study we aim to:

1. Describe how low mood changes across adolescence and adult life and to identify the factors that explain whether low mood improves or worsens over time.
2. Identify which factors help lower the possibility of later difficulties with low mood in young people.
3. Create a method for calculating who is at highest risk of future problems so that they can get help early. The hope is that early help can prevent problems from developing in the future. These sorts of calculators are used in GP surgeries for physical problems like heart disease and we plan to develop one for mood difficulties.

Over the past 10 years we have been carrying out a long-term study, seeing each family several times. We are now looking to see what has changed in the years since we last visited you, and what has remained the same. This long-term study will be important for working out how low mood begins and finding out new ways in which to prevent low mood turning into depression. We are hoping to meet with each young person and their parent again for this phase of the study.

**Who are the researchers?**

The study is being undertaken by doctors and researchers at Cardiff University. The investigators have a lot of experience working in the field of child health and adult depression. This study has been funded by the Jules Thorn Charitable Trust and the Medical Research Council.

**Why have I been chosen?**

You have been invited to take part because you participated in the earlier phases of this study. We are now inviting the same families to take part in this phase.

**Do I have to take part?**

It is entirely up to you whether you would like to take part. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision not to take part or to withdraw will not affect the standard of care, or the services you receive now or in the future.

**What is involved if I take part?**

If you are willing to take part the study will involve the following stages:

1. First, we ring you up to talk more about the study, answer any questions you have and then arrange to visit you at a place and time most convenient to you (e.g. home) for a morning, afternoon or evening.
2. Before we meet we will send you some questionnaires to complete in your own time. They take around 30 minutes to complete and all your responses are confidential. You can either complete an electronic version on your home computer or a paper copy – which ever you prefer.

When we meet, we will complete an interview with you about mood and wellbeing that takes about 2 hours. If you would like, we can split the interview over two different days or take a break in the middle. With your permission, this interview will be tape recorded.

We will also ask you to complete a short computer task or puzzle to look at how you solve problems. We will look at your physical health including height, weight and blood pressure. If you wish to miss out any of the questions or tests, for example if you feel they are too personal, then you are free to do so.

1. We would like to collect a saliva sample of approximately 1 teaspoon will be taken on one occasion over the course of the study. The sample will be collected by the research team, using a plastic tube that you will spit into.
2. We would like to collect a blood sample of approximately 17 ml, (3 teaspoons) using venepuncture, to measure cholesterol and inflammation. For this sample we may give individual feedback about your cholesterol levels if the results of the blood test are not in the normal range. This would be a simple precautionary measure so that you could arrange to discuss the results with your GP. We would usually send any feedback directly to you (the individual taking part) but with your explicit permission we could also forward any test results to your GP. If any feedback is needed this would usually happen within 2 weeks of the sample being taken.

The collection of the samples will only take a short amount of time and be taken over one occasion. All staff have received training in phlebotomy.

With your permission, these samples will be stored and used for future ethically approved research

1. We would also like to ask your permission to link the information you have provided us with to information collected by the NHS and other public organisations (e.g. GP, hospital and education records).

**What will my samples be used for?**

Our research uses the samples and information you have provided to improve our understanding of low mood and depression. The samples we collect may be used in the future by researchers in the UK and abroad undertaking ethically approved research which may include DNA analysis or use by the commercial sector. Your sample will be anonymised and researchers will not be able to identify you from your sample.

**Will I be able to be identified by my sample?**

All samples given will be anonymised and only the researchers will have access to any identifiable information and this will remain confidential. Each sample will be given its own unique sample ID which will not include any of your personal details.

**Will you analyse my DNA?**

As part of this study we intend to carry out analysis of DNA. The type of analyses we will perform are for research purposes and therefore we will not be able to provide any clinical feedback. It will not be possible to identify you from any samples given, all will remain anonymous and confidential.

Any samples you give will be as a gift and you will not benefit financially in the future should this research lead to the development of a new treatment or medical test.

If requested, any unused samples will be disposed of according to locally approved procedures. Any samples used or results generated prior to the withdrawal of consent will continue to be utilised in this study.

**What are the potential risks associated with giving a blood sample?**

Common risks associated with giving blood could be a little pain during and some bruising. These risks will be minimised as all staff are fully trained in phlebotomy. Bruising after the event will also be reduced by promptly applying pressure on the puncture site with cotton wool, after the needle is withdrawn.

Although phlebotomy is a very safe procedure, it does create a puncture wound on the skin which may very rarely lead to infection around the puncture site. The risk of this will be minimised by ensuring strict hygiene during the procedure. Although very unlikely, if you do experience any symptoms of an infection (local redness, swelling, pain or discharge of pus) it is essential you contact your GP or go to A+E urgently.

**When will I be seen?**

We will arrange a visit that is convenient for you in the next few months.

**Why are you asking for my permission to link research data with NHS and education records?**

We plan to examine the links between mental wellbeing, education and health. With your permission, the information you provide for this study may be linked in an anonymous way to routinely collected datasets. These existing datasets, and data that may be collected in the future, contain anonymous health and social record information (for example, general practice records, hospital records). An example of such a databank that we will link to in Wales is the Secure Anonymised Information Linkage (SAIL) dataset at Swansea University. All data linkage is undertaken in line with the Data Protection Act (1998) and University governance. If you agree, linking your research data to NHS and education records, will make the information you have provided even more valuable.

**What happens if I want to take part and another family member doesn’t?**

Ideally we would like each family member to participate, however, we understand this may not always be possible. We are very happy for you to take part even if your parent or child cannot as any information you give is extremely useful and valuable to this project.

**Will anyone be informed about my participation in the study?**

We do not share the research information with anyone, including your GP. The only instance when we would contact your GP would be in exceptional circumstances where we were concerned about your safety of the safety of others (for example if you expressed thoughts of harming yourself or others) and we would reserve the right to speak to your GP about this risk.

**What are the possible benefits of taking part?**

Advantages of taking part in the research include the chance to help increase knowledge and understanding about depression which has been a neglected area of research and to help families where someone has suffered from this condition. In the past, some people have found it useful to spend time thinking about the topics included in the interview and questionnaires.

**What are the possible disadvantages of taking part?**

There are some people who may find it difficult or distressing to discuss certain things such as their mood and how they are feeling. If after participating in this study you feel the need for support, you can contact us on the telephone number on this leaflet. You will also be given a sheet with some useful contact numbers of services that can help with mental health.

**How will my time be reimbursed?**

We understand that time is valuable. Each participant will receive a £20 voucher as a thank you for participation in the study. We will also reimburse any travel costs if you choose to meet us somewhere other than your home (e.g. at Cardiff University).

**Will my taking part in this study be kept confidential?**

All information collected from you (and your family) during the course of this study will be kept strictly confidential in accordance with the Data Protection Act 1998. This means that no-one else knows about your involvement except the people on the research team. Any information about your identity obtained from this research will be kept anonymously (we use identification numbers instead of your name) and it is stored securely and separately from the data collected from you. The genetic material obtained will also be anonymised. Only the study team will have access to your data and only they will contact you directly. There are strict laws that safeguard your privacy at every stage. Your name and identifying information will not be passed on to anyone.

To make the best use of the important information you provide, we will share data (which will be anonymous) with qualified researchers at other hospitals and universities. Any information that leaves the university research site will be made anonymous and will have your name and address removed so you cannot be identified from it. In any sort of report that is published, no information will be supplied that will make it possible for other people to know your name or identify you in any way at all.

We will not share any information given with any other family member, even if they also participate in the study.

**What happens to my samples at the end of the study?**

At the end of the study, samples will be retained by the Division for Psychological Medicine and Clinical Neurosciences, Cardiff University for use in future ethically approved research.

**What will happen to the results of the research study?**

The results will be summarised in an information sheet which will be sent to everyone that takes part at the end of the study. The results will be written up in reports and scientific papers. The results will be presented to doctors, nurses, counsellors, self-help groups and other professionals interested in depression and involved in the care of young people and their families.

**What if I decide I don’t want to be involved in any future studies?**

Your participation in this study and future studies is completely voluntary and you are free to withdraw at any time without giving a reason and without your medical care or legal rights being affected. You may contact the research team via the information given at the bottom of this page to advise us of this decision, your contact details can then be removed from the database and you will not be contacted for any future studies. The samples used or results generated prior to the withdrawal of your consent will continue to be utilised in this study.

**Who is organising and funding this research?**

The research is organised by Dr Frances Rice within the Division for Psychological Medicine and Clinical Neurosciences, Cardiff University. The research is currently funded by the Medical research Council.

**Who has reviewed and approved the study?**

All research projects need to be reviewed by an ethics committee to ensure research is being carried out in an ethical way. This project has been reviewed by the School of Medicine Ethics Committee at Cardiff University.

**Further information and queries**

If you or your family have any concerns about your health, a member of the research team can discuss these concerns with you and any services available to you.

# Contact for Further Information

Emma Meilak (Research Administrator)

MRC Centre for Neuropsychiatric Genetics and Genomics,  
Division of Psychological Medicine and Clinical Neurosciences,  
Cardiff University,   
2nd Floor Hadyn Ellis Building,  
Maindy Road,

Cardiff, CF24 4HQ.

Telephone: 029 2068 8479

Email: [MW-B@cardiff.ac.uk](mailto:MW-B@cardiff.ac.uk)

**Thank you for reading this information. This copy is for you to keep.**

**We would like to thank you for considering to take part in this study. If you decide to participate, you will be given a consent form to sign and keep.**

**Useful contacts**

Here are some useful contacts for free and confidential advice on mental and physical health issues. If at any point you feel you need support relating to your mental health, please contact your GP.

**Saneline**  
Helpline providing information on mental health. Also offers emotional and crisis support to people experiencing mental illness, their family/carers and friends.  
0300 304 7000 (4.30pm-10.30pm every day)  
E-mail: [**sane@saneline.org**](mailto:sane@saneline.org)  
[**www.sane.org.uk**](http://www.sane.org.uk)

**The Samaritans**  
The Samaritans provide 24 hour, confidential, emotional support for anyone in crisis.  
116 123 (24 hours, number free from any phone)  
[**www.samaritans.org**](http://www.samaritans.org/)

**Mind Infoline**

Information service for users of mental health services, carers and other groups. Information on types of mental distress, treatments, therapies and legal information.  
Call: 0300 123 3393 (9am – 6pm, Monday to Friday)

Text: 86463  
E-mail: [**info@mind.org.uk**](mailto:info@mind.org.uk)  
[**www.mind.org.uk**](http://www.mind.org.uk)

**NHS Direct Wales**  
0845 4647

[**http://www.nhsdirect.wales.nhs.uk/**](http://www.nhsdirect.wales.nhs.uk/)

**National Centre for Mental Health (NCMH)**

[**http://www.ncmh.info/**](http://www.ncmh.info/)

**Heart UK the Cholesterol Charity**

[**https://heartuk.org.uk/healthcare-professionals/learning-resources/summary-of-jbs3-and-nice-cg181**](https://heartuk.org.uk/healthcare-professionals/learning-resources/summary-of-jbs3-and-nice-cg181)

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If you are unhappy with the way you were treated or with something that happened during the course of the research project.

In the first instance, contact the leader of the Research Project:

Dr Frances Rice

Division of Psychological Medicine & Clinical Neurosciences

School of Medicine

Cardiff University

Hadyn Ellis Building

Maindy Road, Cardiff

CF24 4HQ

**Tel:** 02920688384 **Email:** [RiceF2@cardiff.ac.uk](mailto:RiceF2@cardiff.ac.uk)Following this, if you are still unhappy, you can be advised on how to contact the relevant Ethics Committee.