A study about how parts of the brain work in people with Down Syndrome

My name is Rosalyn Hithersay. I am a researcher working at University College London. I am carrying out research to investigate differences in cognitive functions (brain functions) in people with Down Syndrome. I will also investigate possible genetic and biological reasons for these differences. The study is funded by the Wellcome Trust and is sponsored by University College London. The study has been reviewed by the North Wales West Research Ethics Committee.

What is the importance of the study?

People with Down Syndrome often differ between one another in their cognitive abilities. These abilities include attention, task planning, memory, language, and coordination of movements. Alzheimer’s Disease occurs more often in individuals with Down Syndrome compared to other individuals. Differences in brain activity may help to explain these differences in individuals with Down Syndrome. This may also explain why some people with Down Syndrome develop Alzheimer’s Disease while others do not.

We are collecting data from a large number of individuals with Down Syndrome to investigate brain activity to help to explain these differences between people with Down Syndrome. This may also explain why some people with Down Syndrome develop Alzheimer’s Disease and others do not. The results of these studies will hopefully improve the care and treatment of individuals with Down Syndrome, and may also help to develop new treatments for Alzheimer’s Disease.

Participants in this study will be asked if we can place a special cap on their head for us to look at their brain activity. This cap contains sensors that use light to measure blood flow in the brain. We will ask participants to sit as still as possible while we record their brain activity. These studies will help us to understand whether differences in brain activity can explain the differences in abilities and the development of Alzheimer’s Disease in individuals with Down Syndrome.

Who is eligible?

We are looking for people with Down Syndrome, aged 16 and older. Participants will need to be able to understand simple instructions and press buttons in response to pictures. We will include people who have stable and treated mental or physical health problems. We will not be able to include people who are currently affected by an acute illness, but they will be welcome to take part when they are better.
We will include people who cannot consent themselves. If someone lacks capacity, we have to seek an opinion from a family member or carer (personal or nominated consultee).

**What will the study involve?**
Participants will take part in an assessment that will last around 2 hours. We will measure their brain activity while they play games on a computer for about forty minutes.

Relatives or carers are welcome to be present during the assessment.

**Where will assessments be done?**
The assessment will take place at University College London. We will reimburse any travel expenses for participants or carers. We will arrange the assessment at a time that is convenient for the participants.

**What happens after the assessment?**
We will give participants a small gift to say thank you for their help. We will tell the participant’s GP they have taken part in the study. We will also pass on details of the assessments given and results to the participants’ GP, if requested.

**What will happen if we notice anything unusual?**
If we notice anything which may be of clinical significance, we will let the care team or GP know. They can then take the appropriate action.

**What will happen to the information collected during the study?**
All personal information and any information we obtain from our studies will be completely confidential and known only to the research team. All of the results from the study will be stored on a database. These will be anonymised (i.e. personal information about participants will not be stored with any data collected about them). The results may be sent to other researchers or shared with other researchers (these will be anonymised). All personal data will be handled in accordance with the Data Protection Act 1998. Personal data will be password protected and securely held on the UCL IT system or locked in a filing cabinet. Access will be restricted to members of the research team. Personal data will be stored separately from all other data. Personal data will not be disclosed without the consent of the participant (or advice from the consultee if the participant cannot consent). However, if there is a serious risk of harm to the participant, yourself or others, or concerns for the neglect
or abuse of the participant, then we will have to share this information with the appropriate agencies. This may be without your or the participant’s permission. If this happens we would discuss it with you and the participant first. If there are health concerns, the participant’s care team or GP may also need to be informed. If this happens we would also discuss it with you and the participant first.

Anonymised paper records will be stored securely within the Faculty of Brain Sciences at University College London. The anonymised brain activity data and recordings will be entered into an electronic database held within the Faculty of Brain Sciences at University College London. Research data will be stored for 20 years following the end of the study, following UCL regulations.

Analysis of the results of the assessment will be performed within University College London. All results will be anonymised, and the anonymisation codes will be accessible only to members of the research team. These will be held securely. Anonymised data may be shared with other research groups who are conducting research in the field of learning disabilities.

We will publish the results from these studies in academic journals, and present them at scientific conferences and meetings. In addition, we will keep the participants informed about how the study is progressing via a regular newsletter. No participants will be identifiable from any publications arising from the study.

We would like to keep a record of participants’ contact details so that we can contact them if we need more information or if we are thinking about doing more research. We will keep this information for ten years following the end of the study.

**What are the risks and benefits of the study?**

There are few risks to potential participants.

Participants are required to sit as still as possible during the recording of brain activity. This may be uncomfortable. To minimise any discomfort felt this recording will only last for around forty minutes and there will be breaks during the recording.

This study will benefit individuals with Down Syndrome as it will increase knowledge about reasons for differences in those with Down Syndrome. This study may also help us to understand how Alzheimer’s Disease develops. This may lead to better care and treatment of individuals with Down Syndrome or Alzheimer’s Disease in the future.

In addition, we will be able to use the brain activity recordings as a baseline to measure future changes against. If requested we will be happy to share these results with the participant’s GP or care team.
**Withdrawing from the study**

If you decide at any time the participant should withdraw from the study, you have the right to withdraw them and not give a reason. Withdrawing from the study or a decision not to take part will not affect any aspects of care for the participant.

**Advice and complaints**

If you wish to complain, or have any concerns about any aspect of the way the participant has been approached or treated by members of staff due to their participation in the research, National Health Service (if they were recruited via the NHS) or UCL complaints mechanisms are available to you. Please ask Rosalyn Hithersay (r.hithersay@ucl.ac.uk, 020 7679 9318) if you would like more information on this. In the unlikely event that the participant is harmed by taking part in this study, compensation may be available to them. If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with Rosalyn Hithersay, please make the claim in writing to Andre Strydom (a.strydom@ucl.ac.uk, 020 7679 9308), who is the Chief Investigator for the research and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. The participant may have to bear the costs of the legal action initially, and you should consult a lawyer about this. **NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm.**

**Thank you for taking the time to read this information sheet**

Please contact me if you have any questions

**Details of contact person**

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