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

Our names are Anna and Mona. We are researchers working at King's College London. We are carrying out research to investigate differences in cognitive functions (brain functions) in people with Down syndrome. We will also investigate possible genetic and biological reasons for these differences. This study is currently being funded by the Jérôme Lejeune Foundation, the Baily Thomas Trust and others. The study is sponsored by King's 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 co-ordination of movements. Alzheimer's disease occurs more often in individuals with Down syndrome compared to other individuals. Genetic and biological differences may help to explain these cognitive 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 some of the reasons that help to explain these differences between individuals with Down syndrome, and 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 given a variety of brain tasks, including remote testing to be done at home using an app downloaded on mobile phones to investigate their abilities. Smartphones to carry out these remote testing tasks will be provided if required. We will ask participants for a blood sample. These studies will help us to understand the genetic and biological factors which affect cognitive 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 30 - 60. Participants will need to be able to understand simple instructions and do simple puzzles and games. 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 which will last 4 - 5 hours. They will be asked to complete various tests (like games) – some of these will be on a touchscreen computer tablet. Relatives or carers will be asked to be present and will be asked to complete questionnaires during this time. Participants will be given a break half way through the assessment, or more as needed.

We will collect some basic information and medical history about the participants from them and their carers. If agreed, we may also discuss participants with their community learning disability teams and look at their patient records.

We will check participants' blood pressure and general physical health. We will also take a blood sample for genetic and biomarker analysis, as well as for cellular analysis (e.g. to see how Down syndrome affects cell development).

Participants will also be asked to complete cognitive tests remotely via an app downloaded on smartphones or tablets whereby domains such as attention and memory are measured.

Where will assessments be done?

The assessment will be arranged at a time that is convenient for the participants. We will reimburse any travel expenses for participants or carers.

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, and we may ask to access their medical records. We will also pass on details of the assessments given to the participants' GP, if requested.

What will happen if we notice anything unusual?

If we notice anything which may be of clinical significance (e.g. if a participant who has not been diagnosed with dementia by the care team has a score suggestive of

dementia on the assessment) 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, including the genetic results, 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 and students (these will be anonymised). All personal data will be handled in accordance with the General Data Protection Regulation (2018). Personal data will be password protected and securely held on the KCL 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 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.

In addition to genetic and health-related data, the study will collect cognitive test and survey data via the ARC-DS mobile application. The app will also collect basic device analytics such as the device model, operating system version, ARC-DS app version, and the general time-zone, to help schedule test availability appropriately. Each participant is assigned a unique ID to log into the app. This ID is not specific to their device and cannot be used to identify the participant—it is unique to the mobile app and remains anonymised.

Anonymised paper records will be stored securely within the Institute of Psychiatry, Psychology, and Neuroscience at King's College London. The anonymised information (including genetic data) will be entered into an electronic database. Research data will be stored for 20 years following the end of the study, following KCL regulations.

Analysis of the results will be performed within King's College London, University College London, or Queen Mary, University of London. Blood samples will be stored anonymously and analysed in laboratories within King's College London, University College London or Queen Mary, University of London, or in some cases other laboratories. Saliva samples will be stored anonymously and analysed in laboratories

within University College London, or in some cases in laboratories outside University College London. Some of the analysis, such as analysis of the blood samples, may have to be performed outside the UK, such as in laboratories or centres in Europe or in the USA. All biological samples will be anonymised when they are collected. The anonymisation codes will be accessible only to members of the research team, and these will be held securely. Anonymised samples may be shared with other research groups. Samples may be stored for use in future research. Anonymised genetic data may be shared with other research groups or entered onto publicly accessible databases. This is standard practice in genetic studies, and the best way to quickly share information about new genetic findings with other researchers and with clinicians across the world.

We will publish the results from these studies in academic journals, and present them at scientific conferences and meetings. Students may use the data for their projects and dissertations. We will keep 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 may feel frustrated and anxious when completing the tasks. To reduce this we will have a break in the middle of the session, and we will give further breaks where appropriate.

Giving a blood sample may cause mild pain, some bleeding and bruising. To reduce pain we can use a cream before taking the sample. 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, the tasks that the participant will complete during this study could be used 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 KCL complaints mechanisms are available to you. Please ask [ ] 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 (King's College London) or the hospital's negligence then you may be able to claim compensation. After discussing with us, please make the claim in writing to Andre Strydom (andre.strydom@kcl.ac.uk), who is the Chief Investigator for the research and is based at KCL. 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.*

If you have questions or wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer at info-compliance@kcl.ac.uk who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

For general information about your rights and your personal data, you can consult the website of the UK Data Protection Act 2018 (https://www.gov.uk/data-protection).
If you have a concern about any aspect of this study, please contact the study team at downsyndrome@kcl.ac.uk.

For independent advice and information you can contact the PALS Service at the South London and Maudsley Patient Advice and Liaison Service (PALS) at pals@slam.nhs.uk or 0800 731 2864, alternatively you can consult the PLAS website www.pals.slam.nhs.uk

Thank you for taking the time to read this information sheet

Please contact us if you have any questions

Details of contact person

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Project title: The London Down Syndrome Consortium (LonDownS): an integrated study of cognition and risk for Alzheimer's Disease in Down Syndrome

IRAS number: 120344

How the participant's personal data will be used in compliance with General Data Protection Regulation (GDPR)

King's College London (KCL) is the lead sponsor for this study based in the United Kingdom. We will be using information from you and the participant's medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after the participant's information and using it properly. KCL will keep identifiable information about the participant for 20 years after the study has finished. The participant's rights to access, change or move their information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. If they withdraw from the study, we will keep the information about them that we have already obtained. To safeguard their rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use their information by contacting the Chief Investigator (Prof. Andre Strydom: andre.strydom@kcl.ac.uk) or visiting the KCL website: https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research.aspx.

King's College London will collect information from the participant and their medical records for this research study in accordance with our instructions.

King's College London will keep their name, NHS number and contact details confidential and will pass this information to King's College London. King's College London will use this information as needed, to contact them about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Certain individuals from King's College London and regulatory organisations may look at their medical and research records to check the accuracy of the research study. The people who analyse the information will not be able to identify them and will not be able to find out their name, NHS number or contact details.

King's College London will keep identifiable information about the participant from this study for 20 years after the study has finished.