



Impact of MEKi on learning

Parental Participant Information Sheet (PIS)

You are being invited to take part in a research study exploring whether MEK inhibitors impact learning, attention and mental health in children and young people with NF1. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ Who will conduct the research?

The study is being run by **Dr Shruti Garg** from **faculty of Biology, Medicine and Health at The University of Manchester (UoM)**, but during the study you will most likely meet two researchers called **Becky** and **Sadali**.

The research is being conducted in collaboration with the Manchester complex NF1 team (at Central Manchester University Hospitals NHS Foundation Trust).

➤ What is the purpose of the research?

About 80% of children with Neurofibromatosis type-1 (NF1) experience difficulties in learning, memory, and attention. Currently there are no NF1 specific treatments available for such difficulties. This study will use a variety of assessments to explore the impact of MEK inhibitors on the learning and psychological functioning of children and young people with NF1. We believe the research findings will help us better understand the neurobiology underlying difficulties related to learning, memory and attention and facilitate us to develop potential targeted treatments for NF1.

➤ Why have we been asked to take part?

You have been invited to take part in this study because your child has NF1 and they are due to commence a new treatment (Selumetinib; a MEK inhibitor). We aim to recruit 25-30 participants with NF1 to this study.

➤ Will the outcomes of the research be published?

The results will be posted on our website and social media pages and published in research journals. They may also be presented at academic conferences. We can also send you a copy of the publications on request.

➤ **Disclosure and Barring Service (DBS) Check**

The researchers involved in this study have undergone a satisfactory DBS check.

➤ **Who has reviewed the research project?**

An independent group of people called a Research Ethics Committee, looks at all research in the NHS to protect your child's safety, rights, wellbeing and dignity. This study has been checked and approved by **NHS North West - Haydock Research Ethics Committee 25/NW/0101**.

➤ **Who is funding the research project?**

This study is funded by the NIHR (National Institute for Health Research) as part of the Mental Health Mission (MHM-TRC) project.

What would my involvement be?

➤ **What would my child and I be asked to do if we took part?**

The research team will explain the study to you in detail to help you decide about taking part in the study. All visits for the study will take part at the same location; either at the Manchester MEK/NF1 clinic or your home. The study will involve 4 research visits lasting up to 3 hours, which we will offer on days you are due to see the clinical team if you choose to do the study at that location. Details of what will happen if you are interested in taking part are described below.

Before the study:

- A researcher will get in touch with you prior to the first research visit to explain the study and go through some basic questions about your child. This will be done to make sure that you and your child fully understand what the study involves and that there are no problems with your child taking part.
 - If you are happy to take part, we will try to plan all 4 visit times/location then.
 - Once you and your child have consented to the study we will also contact your child's GP to let them know they are taking part in this study and gather some brief medical and demographic information.
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During the study visits:

- On the weeks of the research visit, we will send you and your child some electronic questionnaires to complete to make the research visit faster.
- If you haven't had time to complete the questionnaires before the visit, we will do these together during the visit.
- On the day of the visit, two members of our research team will work with you and your child to complete a series of tasks, questionnaires and computer puzzles.
- Your child will also watch some videos and images on a computer whilst having an EEG. They will be video and audio recorded during this time and their eye-movements will be tracked. They will also be wearing monitors for movement and heart rate. These devices have all been designed to be very comfortable, but the EEG cap can leave hair a little messy.

There are also two optional components to the study. If interested your child could also provide a sample of blood at the first and final assessment point. Equally, you and your child can take part in an online interview following the final visit to discuss your experiences of the medication. **The interview would last up to 45minutes and be conducted on Microsoft Teams (MST).**

➤ If we agree to provide a blood sample?

If your child agrees to provide a small blood sample, an additional 5ml of blood (roughly a medicine spoon) will be taken at the regular clinical blood tests. Rather than being tested by the clinical team, this will be taken to a research facility in Manchester Hospital and stored safely for future examination. The sample will be pseudo-anonymised as soon as it is obtained and your child will not be identifiable from this. We would like to use this sample to explore the impact of MEKi on blood to see if this helps us understand how it works.

With your consent, we would also store this for potential future studies. Future studies would not undertake DNA sampling and would only be conducted in the UK.

If you would like further information about what is involved in this research project, please click here: <https://spinlab-uom.github.io/current-studies/currstud-1/>

Will I be compensated for taking part?

We will reimburse all travel expenses. All participants in the study will also receive a £20 gift voucher as compensation for the time taken in the study. This

will be given to you once your participation in the study has come to an end.

➤ **What are the possible risks of taking part?**

Safety of the children taking part in the study is our utmost priority, so if at any point your child feels uncomfortable and wants to discontinue, we will end the procedure safely and quickly. EEG recordings are routinely done in children with NF1 and both EEG and eye-tracking tasks are typically very comfortable and unintrusive. They are safe and involve the child watching various videos or looking at pictures for about an hour total. There are always staff around to reassure the child and we work with families to create the best experience possible for the child.

➤ **Are there any benefits of taking part?**

Your child might not receive any direct benefit, but we hope that this will help better understand researchers more about learning, attention and psychological health in NF1, which in time will allow development of successful interventions.

➤ **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you do decide to take part please contact the research team (details given) or clinical team who can direct you to the appropriate person. You will be given this information sheet to keep and will be asked to review and sign a consent form. If your child is over 16 years old or able to consent for themselves they will also sign a consent form. If they are under 16 years old, they will be given a slightly different sheet but still asked to indicate they are comfortable to take part. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself or impact on your child's care. Should you decide to leave the study part way through you can either choose to withdraw your data or allow us to retain what we have gathered up to that point. **If you decide to remove the data we have already collected you can do this by contacting the research team who will enact your wishes.**

It will not be possible to remove data from the project following the end of the study as it is fully anonymised at this stage and we will not be able to identify your specific data. This does not affect your data protection rights.

If you decide not to take part you do not need to do anything further.

As the blood sample and recorded interview are optional, you and your child are welcome to take part in the rest of the study but decline to do either or both of these elements.

If you agree to participate in the additional interview, this will be conducted online via MST and it will be recorded. You will be allowed to stop the interview at any time.

Data Protection and Confidentiality

➤ What information will you collect about me?

In order to participate in this research project, we will need to collect information that could identify your child, called “personal identifiable information”.

Specifically, we will need to collect:

- Name
- Gender
- Date of birth
- Address and contact details
- GP details
- Medical history and family details

For those participating in the interview we will also collect a video recording (of the interview).

➤ Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ What are my rights in relation to the information you will collect about me?

You and your child have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about your child.

Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](https://documents.manchester.ac.uk/display.aspx?DocID=37095) (<https://documents.manchester.ac.uk/display.aspx?DocID=37095>).

➤ **Will my child's participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, UoM is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- The study team will store your identifying information (name and contact details) securely and separately from your study data.
- Study data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the research team. Once all of the data has been analysed, we will destroy the key, fully anonymising the data.
- Your consent form (including your name and signature) will be retained separately for 5 years after the end of the study in a locked filing cabinet on University premises. We will also ask for your permission to keep your contact details on file for 5 years to contact you about future studies that you might be interested in.
- In accordance with the UoM's Research Privacy notice and with your consent, we would like to be able to share your anonymised data with other researchers who are doing studies similar to ours. With your consent your anonymised information will be shared in order to support additional research in accordance with UK Policy Framework for Health and Social Care Research (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>). This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.
- At the end of the project we would like to deposit a fully anonymised dataset in an open data repository where it will be permanently stored. We will use Figshare at the UoM Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

For those Participating in interview:

In order to ensure that we have an accurate record of our conversation, we need record it using the MST software. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on UoM managed file storage as soon as possible following the completion of data collection.

The recording will include both your voice (audio) and your face (video). If you prefer, you can disable your camera so that only your voice is recorded. The recording will be used by Becky (a UoM researcher) to make a transcript of the recording and once we have checked that the transcript is correct, the recording will be deleted. We will remove any information from the transcript that might identify you.

So that we can provide the shopping/Amazon voucher as a thank you for your time, your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used for them for any other purpose.

➤ **Are there any people that will be told about my child's involvement in the study?**

Your child's GP and clinical team will be informed of their participation in the study but specific details of things that happen in the study will only be shared under certain circumstances such as:

- If, during the study, we have concerns about your safety or the safety of others, we will inform your GP/care team/family member as needed.
- If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this and will therefore need to inform your employer/professional body.
- Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

➤ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact:

Dr Shruti Garg

Tel. - 0161 3067967

Email – shruti.garg@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:

research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](https://ico.org.uk/complaints/) Tel 0303 123 1113

➤ Harm

In the unlikely event that something does go wrong and you or your child are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Contact Details

If you have any queries about the study or if you are interested in taking part, please contact:

Becky by emailing NFresearch@manchester.ac.uk