

Impact of MEKi on learning?

(Short) Information sheet for Children and Young People

Why should I read this?

You are being invited to take part in a research study. 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 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.

For extra information please follow... (can we link to something else (<https://www.manchester.ac.uk/discover/privacy-information/data-protection/privacy-notices/>))

What is this study?

This study is going to explore how a type of tablets (called MEK inhibitors/MEKi) impact learning, attention and mental health in children and young people with Neurofibromatosis (NF1).

Why is this study happening?

A lot of children with NF1 can struggle with learning and attention and they can also struggle with their mental health. Currently there are no specific treatments available for such difficulties. This study will use several different tasks to look at the impact of MEKi tablets (the medication you are thinking of starting) on several psychological areas (including learning, attention and mood) in children with NF1. We believe the research findings will help us better understand these difficulties and help us to develop future treatments for NF1.

Why have I been asked to take part?

You have been invited to take part in this study because you have NF1, are due to start MEKi treatment, and you're under 18 years old.

Do I have to take part?

Not at all. It is entirely up to you if you would like to take part in the study. If you agree to take part, we will ask you and your parent/carer to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard or type of care you receive.

What happens next?

If you're interested, let your clinical team know or contact the research team directly by emailing nfresearch@manchester.ac.uk.

The research team will call and explain the study to you in detail to help you decide about taking part in the study and will double check there are no problems with you taking part in the study.

What will happen if I take part?

All visits for the study will take part either at Manchester Hospital (when you come for

a health appointment) or if you prefer, they can take place at your home. The study will involve 4 research visits which can last between 2-3 hours.

What does a research visit involve?

1. On the day of the visit a member of our research team will work with you to watch some videos and complete some computer tasks and answer some questions.
2. For some of the visit you will be wearing an EEG cap and monitors for your movement and heart rate. Your eye and head movements will also be recorded during this time. These devices have all been designed to be very comfortable, but the EEG cap can leave your hair a little messy.
3. Your parents/carers will also be asked to complete some questionnaires during the visit.
4. We will send you and your parent/carer some electronic questionnaires ahead of each visit to make the research visit a little faster.
If you haven't had time to complete the questionnaires before the visit, don't worry, we will do these together during the visit.

Optional:

There are also 2 optional parts of the study which we can discuss if you're interested to hear about them.

Are there any risks or side effects to taking part?

There won't be any 'side effects' because it's not that type of study. We're only looking at the impact of medication you're taking for your physical health and won't be giving you anything new. We don't expect any risks from the study. Your safety and comfort are really important to us so we've taken care to make the study as safe and comfortable as possible. All the tasks and activities have been done lots of times with other children and young people and they are not known to cause distress or discomfort. But, if at any point you in the study you feel uncomfortable and want to stop, we will end the activity.

Are there any benefits?

You will get £20 gift voucher to say thank you at the end of the study. But we think the biggest benefit is that you will have helped us understand more about NF1 and support future children and young people with NF1.

Who will conduct the research?

The study is being run by Dr Shruti Garg from The University of Manchester (UoM), but during the study you will most likely meet two researchers called Becky and

Sadali. The funding comes from '**National Institute for Health Research (NIHR)**'.

The legal bits

We follow all the usual processes around confidentiality and data security that studies of this kind follow- and we take it seriously. More information about this can be found on the information sheet given to your parents or carers or at this website: <https://documents.manchester.ac.uk/display.aspx?DocID=37095>.

Feedback and complaints

We're really keen to hear about your experiences of the study and provide everyone with a feedback form and opportunity to talk about this at the end of the study. If however, you have concerns about any aspect or don't feel comfortable talking to someone directly from the study, please contact either:

Dr Shruti Garg

Tel. - 0161 3067967

Email – shruti.garg@manchester.ac.uk

Or

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

The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674.

More information

If you would like to know more about this study, please contact Becky at: nfresearch@manchester.ac.uk

Alternatively, there are other versions of this information leaflet, videos of the procedures and more information available here <https://spinlab-uom.github.io/current-studies/currstud-1/>

This Project Has Been Approved by the NHS North West - Haydock Research Ethics Committee 25/NW/0101

Thank you for reading through this information sheet and considering participating in our study.