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Participant Information Sheet: 16 years plus

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QbTest Utility for Optimising Treatment in ADHD (QUOTA)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team members or clinician will go through the information sheet with you at your clinic appointment and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear. If you wish to talk to us about the study please email or call (details provided at the end). We are happy to call you back if you prefer.

Local Research Team: If you have any questions about the research, please contact the research team (details provided at the end) in the first instance. If you would specifically like to speak to your clinical team about the research please contact [insert clinical lead name] email [insert email] telephone [insert email].

What is the purpose of the project?

When a child or young person with ADHD is prescribed medication to treat their symptoms, it can be difficult for doctors to tell whether the medication is working. A new computerised assessment called 'QbTest' has been designed to try and improve the measurement of ADHD symptoms. This study is investigating whether this new assessment improves the way healthcare professionals give medication to manage these symptoms in children and young people. In a couple of clinics in the UK QbTest is already part of standard practice, however, this is not the same for all clinics.

Why have I been invited to participate?

You are being invited to take part because you are starting or due to start medication for ADHD.

Do I have to take part?

No. It's your choice. If you do decide to take part we would like you to sign a consent form and return it in the pre-paid envelope included. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights. If you do not take part, the quality of your care will not be affected.

What will happen to me if I agree to take part?

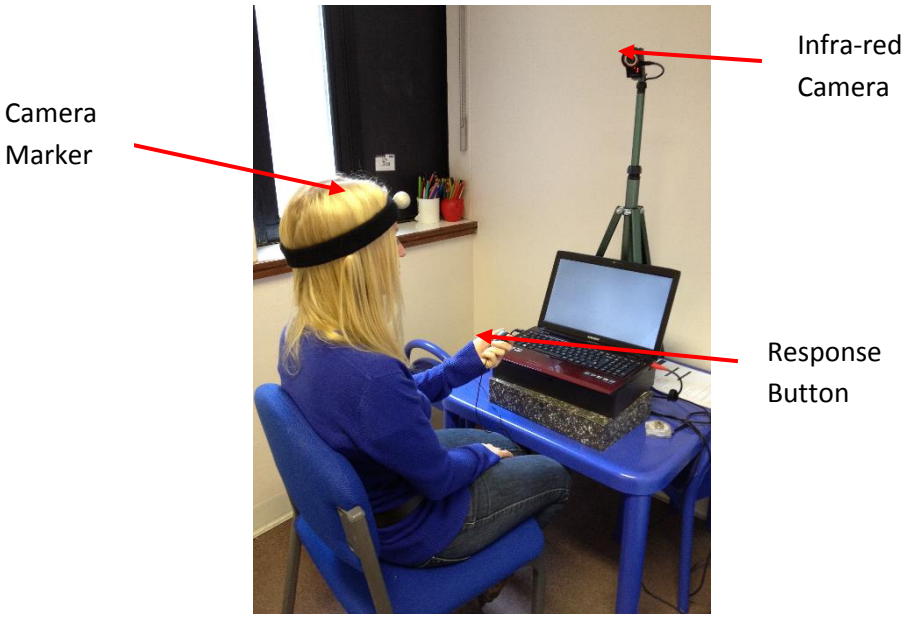
At the beginning of the study the research team will randomly allocate you to one of two groups. One group is the 'QbTest group'. If you are in this group you will receive standard care and will also be asked to complete the QbTest up to 3 times. The other group is the 'standard care group'. If you are in this group they you will receive standard care only and will not complete the QbTest at any appointment. This is so we can see how helpful the QbTest is. Regardless of which group you are in, you will still receive standard care practice.

To perform the QbTest assessment you will be asked to sit on a stool in front of a computer (shown in the picture below). A picture showing the set-up of the assessment is shown below. It consists of an infra-red camera, a head band with an infra-red marker ('camera marker') and a hand-held response button. You will be asked to wear the headband throughout the assessment. During the computer task a number of symbols are shown on the screen. You will be asked to press the responder button when a certain symbol appears on the screen. While you perform the task your movement will be measured by the infra-red camera and recorded. You will not be filmed during the test. The camera only records the movement of the infrared marker. The assessment provides information about your attention, activity levels and impulsiveness. A researcher or clinician will explain the procedure to you fully and will also be able to answer any questions you may have.

If you are placed in the 'QbTest group' you will have to complete QbTest 2-3 times in the clinic:

1) A baseline assessment will be carried out before you start taking medication if you didn't complete a QbTest as part of your diagnosis
2) 2-4 weeks after starting medication
3) 8-10 weeks after starting medication

The results of the assessment will provide you, your parents/carers and the clinical team with extra information about your ADHD symptoms and about any change in symptoms after starting medication.



What else does the study involve?

We will also ask you and your parents/carers to complete some questionnaires in your own time (at home). At the start of the study there will be three questionnaires to complete that ask about your symptoms and how you feel in general (these questionnaires are called: the SNAP-IV, the SDQ and the CHU9D). The SNAP-IV and SDQ must be completed by a parent/guardian. We would encourage you to complete the CHU9D yourself, it is very easy to complete.

When you complete the first QbTest on medication (approximately 2-4 weeks later) we shall ask you and your parents to complete two of the questionnaires again (SNAP-IV and CHU9D), we shall also ask you to complete another questionnaire that measures side effects of medication and ask you if you have been taking your medication every day.

When you complete the second QbTest on medication (approximately 8-10 weeks later) we shall ask you and your parents to complete four questionnaires (SNAP-IV, CHU9D, side effects and ask if you have been taking your medication) and also your parents will be asked to complete an additional questionnaire on any financial costs relating to your ADHD.

If you are not in the 'QbTest group' we shall still ask you and your family to complete the questionnaires at each time point.

The questionnaires can be completed over the phone, by post or online (except the SDQ which cannot be completed online). We will provide more information on how to complete these at the relevant time.

We are also interested in knowing your thoughts on the task. We shall ask some parents and young people to take part in telephone interviews with the research team to understand what you thought of the QbTest, your experience of ADHD medication, and what we can do to improve the way we conduct research in the future.

We will contact your teacher and ask them to also complete a questionnaire about your functioning at school. We will only contact your teacher if we have permission to do so.

Expenses and payments

It is unlikely you will encounter any additional financial costs as a result of taking part in this study. However, it may be that you see your doctor more often which might mean you or your parents/carers may incur additional car parking and travel expenses. We shall give you £20 vouchers to compensate you for the time you have to spend completing questionnaires. £10 vouchers will be given after we receive the first set of questionnaires and £10 at 8-10 weeks when the final questionnaire is complete.

What are the possible disadvantages and risks of taking part?

There are no anticipated disadvantages or risks of taking part in this study. However, if you are placed in the 'QbTest' group of the trial you will have to complete QbTest twice on medication (and once before medication is started if you did not receive a QbTest as part of your assessment process). This means you may have to come to the clinic more often. If you are in the 'standard care' group you will not be able to sit the QbTest on medication, this means you may feel you are missing out, however, the QbTest is not a standard part of practice and your normal care will not be affected.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get from this study may help doctors understand the difficulties that children and young people attending this clinic (and similar clinics) may be experiencing. You and your parents/carers may also find the results of the computer test (QbTest) interesting. We have conducted previous research using this task and parents and young people often find the results really interesting and are glad they took part.

What happens when the research study stops?

We will publish the findings from our study and contact you and your parents/carers with the results if you have said you would like to be kept informed. Your name will not be mentioned in any published report. After taking part in the study your clinical care will continue as normal.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Initially you can contact the lead researcher, Dr Charlotte Hall by email: charlotte.hall@nottingham.ac.uk or telephone: 0115 82 32438, or you can contact Dr Maddie Groom, the chief (lead) investigator on the study team, by email: Maddie.groom@nottingham.ac.uk or by telephone: 0115 82 30267. The researchers contact details are also given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this via the contact the Research and Innovation office (RandIenquiries@nottshc.nhs.uk/ 0115 9691300 ex11903/11904).

Any safeguarding issues will be alerted to the responsible lead clinician and their clinical team and the Trust policy will be followed.

What will happen if I withdraw from the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reasons, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Will my taking part in this project be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. We will not have access to your medical records, only the normal clinical team will be able to access these.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) may be kept for up to 12 months after the end of the study if you give explicit consent for us to contact you about the findings of the study. The data from the QbTest (research data) will be kept securely for 5 years. After this time your data will be disposed of securely. During

this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data. A copy of your QbTest results will also be kept by Qbtech, the company that designed QbTest. They will keep a record of your test results until the clinic removes it or requests QbTest to remove it. This data will be stored anonymously and secured and encrypted and cannot be linked back to you. No personal information will be stored by Qbtech. If you would like your data to be removed, please contact your clinician.

What will happen to the results of the research project?

We will write a report about the project once it has finished (2019). All reports are written anonymously, as such your/your parents/carers name or identifiable details will not be disclosed.

We hope that you might find the report we write interesting too, and you will be able to contact us to discuss the findings towards the end of the research. We aim to circulate the report widely and publish the findings in a medical journal. We shall provide you with a summary of the results when the study has finished.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute of Health Research (NIHR) Research for Patient Benefit (RfPB).

Who has reviewed the project?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by West of Scotland REC 1, Tel: 0141 232 1807, email: WoSREC1@GGC.scot.nhs.uk. The project has also been reviewed by the Health Research Authority. The Research and Innovation team within Nottinghamshire Healthcare NHS Foundation Trust have also undertaken sponsor review in accordance with Trust policies and procedures.

Contact for further information

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