QbTest Utility for Optimising Treatment in ADHD (QUOTA)

This study is not yet open for participant recruitment.

Verified December 2017 by Nottinghamshire Healthcare NHS Trust

Sponsor:
Nottinghamshire Healthcare NHS Trust

ClinicalTrials.gov Identifier:
NCT03368573

First Posted: December 11, 2017
Last Update Posted: December 11, 2017

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Information provided by (Responsible Party):
Nottinghamshire Healthcare NHS Trust

Purpose

Attention Deficit/Hyperactivity Disorder (ADHD) is a condition that affects 3-5% of young people under 18-years-old.

Young people with ADHD have difficulties with attention, impulsivity and hyperactivity that make it harder for them to learn, form relationships and prepare for adulthood. Clinical guidelines state that young people taking medication for ADHD should be closely monitored and have their medication reviewed regularly to ensure they receive the correct dose to improve their symptoms. However, many young people aren't monitored as closely as guidelines recommend. This can lead to lack of improvement or worsening of symptoms meaning that children may not experience the benefits of medication as quickly as they should. At the moment, assessing whether or not medication is working relies on the opinions of teachers and parents, collected through questionnaires. The difficulties of this are: differences of opinion between people, lack of information provided by them, and not returning the questionnaires. A test performed on a computer (QbTest) provides doctors with a report of the young person's symptoms and can therefore show whether medication is working. This may help doctors reach accurate decisions about medication dose more quickly, reducing the need for questionnaires. The study team met with families and young people with ADHD and medical experts and developed a procedure for using QbTest to measure medication effects. The study team will measure how well this procedure works in the real world by asking a group of young people to complete the test when they first start taking medication and at their follow-up appointments. The study team will ask doctors and families/young people for their opinions on the procedure.

The study team shall share our findings with other researchers and with the public by attending local support groups and providing summaries of the study results. The findings will be used to prepare for a future study.

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<tr>
<th>Condition</th>
<th>Intervention</th>
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<tr>
<td>ADHD</td>
<td>Device: QbTest</td>
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</table>
Participants in the experimental arm (QbTest) protocol will also undergo standard assessment as usual plus a QbTest. If a QbTest was not conducted within 12 weeks prior to starting medication (as part of the ADHD diagnostic assessment procedure) the young person will sit a QbTest at baseline (off medication). Once on medication they will sit another QbTest 2-4 weeks after commencing medication and again 8-10 weeks later (and no later than 12 weeks).

Participants in the control arm will undergo standard treatment as usual for ADHD. This will involve the clinician reviewing the child's symptom improvement once on medication and altering the dose according to their clinical judgement which may be informed by rating scales (completed by the parent, teacher and/or young person) and interviews with the parent and young person.

Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: Optimising Medication Management in Children and Young People With Attention Deficit Hyperactivity Disorder (ADHD) Using an Objective Measure of Attention, Impulsivity and Activity (QbTest): a Feasibility Study

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
U.S. FDA Resources

Further study details as provided by Nottinghamshire Healthcare NHS Trust:

Primary Outcome Measures:
- SNAP-IV [ Time Frame: Follow up 2 (8-10 weeks) ]
SNAP-IV is a short questionnaire designed to assess ADHD symptoms, with established validity, reliability and use in clinical and research settings. Completed by Parents and Teachers.

Secondary Outcome Measures:
- SDQ [ Time Frame: Baseline (0 weeks), Follow up 2 (8-10 weeks) ]
The SDQ is a short, well validated and well used clinical and research measure that assesses a range of behavioural and emotional issues in children and young people. Completed by parents and teachers.

- CHU9D [ Time Frame: Baseline (0 weeks), Follow up 1 (2-4 weeks), Follow up 2 (8-10 weeks) ]
a short (5 minute) measure of quality of life. The CHU9D has been designed for use with children and young people and is very easy to complete

- CGI (Clinical Global Impressions Scale) [ Time Frame: Baseline (0 weeks), Follow up 2 (8-10 weeks) ]
Clinicians will be asked to complete the CGI. The CGI takes no longer than 5 minutes to complete and measures symptom severity and improvement due to medication.

- Health Economic Outcome [ Time Frame: Follow up 2 (8-10 weeks) ]
Measure of use of Health Services

- Side Effects Questionnaire [ Time Frame: Follow up 1 (2-4 weeks) and Follow up 2 (8-10 weeks) ]
To measure medication side effects

- Medication adherence [Time Frame: Follow up 1 (2-4 weeks) and Follow up 2 (8-10 weeks)]
  To look at medication adherence

- Qualitative Interviews [Time Frame: Follow up 2 (8-10 weeks)]
  To look at the acceptability of the intervention

Estimated Enrollment: 60
Anticipated Study Start Date: December 2017
Estimated Study Completion Date: March 2019
Estimated Primary Completion Date: March 2019 (Final data collection date for primary outcome measure)

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<tr>
<th>Arms</th>
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<tr>
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<td>Participants in the control arm will undergo standard treatment as usual for ADHD. This will involve the clinician reviewing the child's symptom improvement once on medication and altering the dose according to their clinical judgement which may be informed by rating scales (completed by the parent, teacher and/or young person) and interviews with the parent and young person.</td>
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<td>Experimental: Experimental Arm</td>
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<td>Device: QbTest</td>
<td>QbTest is a computerised assessment which takes approximately 20mins. The test combines a continuous performance test alongside an infrared camera which measures the participant's movements. The infrared camera measures motor activity of the participant whilst they undertake the task. During the test, the participant is presented with continuously changing stimuli. Embedded within these stimuli is a given target. Participants have to respond by pressing a hand-held button only when the target appears. Attention is measured through omission errors and reaction time to response. Impulsivity is assessed through commission errors and anticipatory errors. Motor activity is measured through head movements during the task. The test is approved by the FDA (Ref: K133382) and CE marked.</td>
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**Detailed Description:**
The primary objective of the study is to assess the feasibility and acceptability of the study design using a feasibility RCT.

The end-points to assess this objective are:
Acceptability of randomisation. The number of patients who do not participate and state randomisation as the reason for non-participation. The study team shall also monitor drop-out rates immediately after randomisation and the number of errors in randomisation at each site.

Acceptability of study design. The number of eligible patients at each site and the numbers who consent to take part/withdraw. Withdrawal rates will be recorded alongside time point in the trial to ascertain acceptability of the study duration.

Acceptability of outcome measures. Completion rates for outcomes to determine most appropriate methods of data collection.

Acceptability/feasibility of protocol. Record non-adherence of healthcare professionals to the protocol and explore reasons.

Feasibility of future RCT. Estimate the hours per week needed to run the RCT and therefore the number of research assistants/fellows required and time commitment required by HCPs.

### Eligibility

**Information from the National Library of Medicine**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 6 Years to 17 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

### Criteria

**Inclusion Criteria:**
- Male or Female, aged 6-17 years (at the time of consent).
- Participant is willing and able to give informed consent for participation in the study (if over 16-years).
- Parental consent for children and young people aged under 16-years-old.
- Referred to CAMHS or Community Pediatric services and diagnosed with ADHD.
- Clinician and family (parent/carer and young person/child) agreement to commence stimulant medication for ADHD symptoms.

**Exclusion Criteria:**
- Unable to give informed consent
- Severe learning difficulty
- Not started on stimulant medication (either not started on medication at all or started on a non-stimulant medication)
- Non-fluent English

### Contacts and Locations

**Information from the National Library of Medicine**

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03368573

**Contacts**

Contact: Maddie Groom, Dr +44 (0) 115 82 30267 maddie.groom@nottingham.ac.uk

**Sponsors and Collaborators**

Nottinghamshire Healthcare NHS Trust
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<td><strong>Product Manufactured in and Exported from the U.S.:</strong></td>
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<td><strong>Additional relevant MeSH terms:</strong></td>
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