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QbTest Utility for Optimising Treatment in ADHD (QUOTA)

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
10/04/2018

Overall study status
Completed

Last Edited
28/06/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
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 researchers met with families and young people with ADHD and medical experts and developed a procedure for using QbTest to measure medication effects. The aim of this study is to 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.

Who can participate?
Patients aged 6-17 years (may turn 18 during the study) with ADHD

What does the study involve?
Participants are randomly allocated into one of two groups. If they are allocated into the intervention group, the participant is asked to undertake a QbTest if they have not had one in the last 12 weeks. The participant then begins taking stimulant medication. At the first follow up at 2-4 weeks, the participant undertakes a 2nd QbTest, and again at follow up 2 (8-10 weeks). Once follow up 2 has been completed, the participant is asked to take part in an interview to discuss the acceptability of the intervention. If they are allocated into the treatment as usual group, the participant starts taking stimulant medication. Follow up 1 and follow up 2 are clinic

contact. These can either be via phone or in person consultations, based on clinician's judgement and are to occur between weeks 2 and 10. Once follow up 2 has been completed, the participant is asked to take part in an interview to discuss the acceptability of the intervention.

What are the possible benefits and risks of participating?
The researchers cannot say that any participants may receive any benefit from taking part, but those in the intervention group will take up to two QbTests and in a previous study conducting QbTests, the children, young people and families found these test results really interesting. The study findings may help health professionals to understand the difficulties that children and young people attending an ADHD clinic may be experiencing. There are no anticipated risks for those taking part in the study.

Where is the study run from?
1. Grantham and District Hospital (UK)
2. Medway Maritime Hospital (UK)
3. Acorn Centre (UK)

When is the study starting and how long is it expected to run for?
April 2017 to March 2019

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Laura Williams
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Study website
http://www.institutemh.org.uk/quota

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03368573

Secondary identifying numbers
36253

Study information

Scientific 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

Acronym
QUOTA

Study objectives
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 trialists met with families and young people with ADHD and medical experts and developed a procedure for using QbTest to measure medication effects. They 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. They will ask doctors and families/young people for their opinions on the procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 1, 07/11/2017, ref: 17/WS/0209

Study design
Randomised; Interventional; Design type: Treatment, Active Monitoring

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Mental health, Primary sub-specialty: Learning disorders - ADHD; UKCRC code/ Disease: Mental Health/ Behavioural and emotional disorders with onset usually occurring in childhood and adolescence

Interventions
Following consent into trial by a health care professional, the participant will be randomised by a health professional. Method of randomisation: block randomisation

If randomised into the intervention arm, the participant will be asked to conduct a QbTest if they have not had one in the last 12 weeks. The participant will then commence stimulant medication. At the first follow up at 2-4 weeks, the participant will undertake a 2nd QbTest, and again at follow up 2 (8-10 weeks). Once follow up 2 has been completed, the participant will be asked to take part in a qualitative interview to discuss the acceptability of the intervention.

If randomised into the treatment as usual arm, the participant will commence stimulant medication. Follow up 1 and follow up 2 are clinic contact. These can either be via phone or in person consultations, based on clinician's judgement and are to occur between weeks 2 and 10. Once follow up 2 has been completed, the participant will be asked to take part in a qualitative interview to discuss acceptability of the intervention.

Total duration of treatment and follow up: 12 weeks

Intervention Type
Other

Primary outcome measure
The feasibility and acceptability of a QbTest medication management protocol; Timepoint(s): End of study:

1. Acceptability of randomisation assessed by collecting information on the number of patients who declined to take part and stipulated a reason connected to randomisation. Drop out rates will also be monitored immediately after randomisation, as will the numbers of errors in randomisation
2. Acceptability of the study design assessed via collecting data on the amount of eligible patients, participants approached, declined, consented, randomised, and complete the trial
3. Acceptability of outcome measures assessed via completion rates for outcome measures. This data will be split by data collection method to assess whether online, phone or postal paper based methods are the most appropriate formats
4. Acceptability and feasibility of the protocol assessed by recording non adherence of health professionals to the protocol and further exploration of reasons for non adherence
5. Feasibility of a future RCT assessed through the collection of the amount of time healthcare professionals required to carry out study tasks, as well as time taken by the research assistants /fellows

Secondary outcome measures
1. ADHD symptoms, assessed using the Swanson, Nolan and Pelham Teacher and Parent Rating Scale (SNAP-IV) at baseline, follow-up 1 (2-4 weeks) and follow up 2 (8-10 weeks)
2. Behavioural and emotional issues, assessed using the Strength and Difficulties Questionnaire (SDQ) at baseline and follow up 2 (8-10 weeks)
3. Child's health related quality of life, assessed using the Child Health Utility 9D (CHU9D) at baseline, follow up 1 (2-4 weeks) & follow up 2 (8-10 weeks)
4. Symptom severity, assessed using Clinical Global Impression (CGI) at baseline and follow up 2 (8-10 weeks)
5. Cost associated with use of health services and other costs that the families incurred, assessed using Health Economic Outcome Questionnaire at follow up 2 (8-10 weeks)
6. Side effects of medication, assessed using Side Effects Questionnaire at follow up 1 (2-4 weeks) and follow up 2 (8-10 weeks)
7. Whether medication was taken, assessed using the Medication Adherence Questionnaire at follow up 1 (2-4 weeks) and follow up 2 (8-10 weeks)
8. Acceptability of the intervention to parents/guardians and children and young people, and clinicians, assessed using qualitative interviews after the participant has completed follow up 2 (12 weeks)

Overall study start date
01/04/2017

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Age 6-17 years (may turn 18 during the study)
2. Confirmed clinical diagnosis of ADHD
3. Joint clinician/parent/young person decision to start stimulant medication for ADHD or review effectiveness of medication in CAMHS or Community Paediatric services
4. Capable of providing written consent
5. Parental consent (under 16 years)

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Unable to give informed consent
2. Severe learning difficulty
3. Not started on a stimulant medication (e.g. non-stimulant medication is prescribed or the family choose not to start medication at all)
4. Non-fluent English

Date of first enrolment
11/12/2017

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Grantham and District Hospital
101 Manthorpe Road
Grantham
United Kingdom
NG31 8DG

Study participating centre
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
Acorn Centre
306 London Road
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RM7 9NH

Sponsor information

Organisation
Nottinghamshire Healthcare NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04ehjk122

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1215-20026

Results and Publications

Publication and dissemination plan

The trialists will share their 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. Study findings will be published in clinical academic journals as well as presented at relevant national conferences and meetings within a year of the end of the overall trial end date.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/02/2018		Yes	No
Participant information sheet	version V1.1	10/10/2017	10/04/2018	No	Yes
Participant information sheet	version V1.1	10/10/2017	10/04/2018	No	Yes
Participant information sheet	version V1.1	10/10/2017	10/04/2018	No	Yes
Participant information sheet	version V1.1	10/10/2017	10/04/2018	No	Yes
Participant information sheet	version V1.1	10/10/2017	10/04/2018	No	Yes
Protocol article	developing the protocol	18/06/2019	21/06/2019	Yes	No
Results article		16/03/2021	28/06/2022	Yes	No
HRA research summary			28/06/2023	No	No