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Comparing the effects of providing clinicians and patients with the results of an objective measure of activity and attention (QbTest) versus usual care on diagnostic and treatment decision making in children and young people with ADHD

Submission date
04/07/2016

Recruitment status
No longer recruiting

Registration date
04/07/2016

Overall study status
Completed

Last Edited
18/08/2023

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 common disorder that affects behaviour. ADHD can present in a number of ways, but common symptoms include a short attention span, restlessness, hyperactivity and impulsiveness. In recent years, the number of children recognised and treated for ADHD in the UK has increased dramatically, with spending on medication for ADHD increasing seven fold between 1998 and 2005. Despite this growing demand, clinical methods for the assessing and treating ADHD have hardly changed over the past 30 years. The best current method used to identify ADHD relies on lengthy clinical interviews and observations or questionnaires. However, in real-world NHS practice (i.e. outside research centres), it is generally not possible to apply this level of rigor to all referrals due to constraints on clinic resources and missing data. This study will assess whether providing clinicians and patients with the results of an objective test of activity and attention (QbTest) leads to earlier correct diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD).

Who can participate?
Children aged between 6-17 years who have been referred for ADHD assessment.

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups undergo routine tests for ADHD. This varies between different clinics and treating clinicians, however generally involves an interview with the parent and young person and the completion of a range of questionnaires. Whilst attending the clinic, the participant also completes the QbTest (15-20 minute computerised task in which the patients respond to different shapes on a screen as quickly and accurately as possible while their activity is recorded using infrared tracking). For participants in

the first group, clinicians will have immediate access to the QbTest report to help them with their diagnostic decision making. For participants in the second group, clinicians and patients are not given access to their QbTest reports for six months. After six months, the number of clinic sessions needed until a confirmed diagnosis is achieved is recorded, as well as the time to diagnosis and length of clinic visits.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Nottinghamshire Healthcare NHS Trust (lead trust) and eight other NHS trusts in England (UK)

When is the study starting and how long is it expected to run for?
January 2014 December 2016

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

Who is the main contact?
Dr Charlotte Hall

Study website
http://www.clahrc-em.nihr.ac.uk/clahrc-em-nihr/research/enhancing-mental-health/aqua-trial.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16812

Study information

Scientific Title
A randomised controlled trial comparing the effects of providing clinicians and patients with the results of an objective measure of activity and attention (QbTest) versus usual care on diagnostic and treatment decision making in children and young people with ADHD

Study objectives
The aim of this study is to assess whether providing clinicians and patients with the results of an objective test of activity and attention (QbTest) leads to earlier correct diagnosis than standard care without the QbTest.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands – Coventry and Warwickshire, 11/06/2014, ref: 14/WM/0166

Study design
Randomized; Interventional; Design type: Treatment, Diagnosis, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Learning disorders

Interventions
The study consists of two arms, QbOpen (QBO) whereby the patient and clinician have immediate access to the QbTest report which can be used to inform clinical decision making and QbBlind (QbB) whereby the patient and clinician do not have access to the QbTest report until 6 months after study initiation.

After obtaining consent, participants are randomised on a 1:1 ratio into either the QbOpen (QbO) arm or QbBlind (QbB) arm of the trial. For participants randomised to QbO, clinicians will have immediate access to the QbTest report to inform their diagnostic decision making. For participants randomised to the QbB arm, clinicians and patients will not have access to their QbTest reports until 6 months after the baseline assessment. With the exception of withholding QbTest reports, the procedures are identical for the two arms.

Intervention:
Participants undergo their standard ADHD assessment as usual practice. This varies from clinic to clinic, and between cases and clinicians, however, it would typically involve an interview with the parent and young person and collection of questionnaires and outcome measures from the parent/young person and teacher. Whilst attending the clinic, the participant will be asked to complete QbTest at some point during their initial clinic visit.
Parents are asked to complete the SNAP-IV regardless of their child's age (Swanson et al., 1983) at baseline assessment. The SNAP-IV is a short 26-item questionnaire designed to assess ADHD symptoms, with established validity, reliability and use in clinical and research settings. The SNAP-IV is posted to the participant to complete before the child receives medication or offered the option to complete it online. Teachers are also be contacted by the researcher to complete the SNAP-IV.
The parents are asked to complete the CSRI (Beecham & Knapp, 1992) at baseline assessment. The CSRI asks questions pertinent to economic factors that may alter as a result of the intervention. The questionnaire can be completed at clinic, via the phone, posted to the participant's home address or completed online. Young people together with their parents will be asked to complete an EQ-5D-Y (Wille et al., 2010) The EQ-5D-Y is a short 15-item questionnaire which assesses health related quality of life.
After the first appointment and before the young person starts medication the parent and teacher will be asked to complete the DAWBA (Goodman et al., 2000). The DAWBA is a well validated semi-structured diagnostic assessment interview for common child mental health problems, including ADHD, which includes the SDQ (Strengths and Difficulties Questionnaire; Goodman, 1997) as part of its initial screen.
Patients who receive a diagnosis of ADHD and are allocated by clinicians to receive ADHD medication initiated within 3 months of their baseline assessment are asked to complete a 2nd QbTest (Qb2) 4-8 weeks after medication initiation. This timeframe was chosen to ensure that all participants can complete their second QbTest before the 6-month follow-up.
At 4-8 weeks post medication initiation, parents and teachers are also be asked to complete the SNAP-IV (either at clinic where researcher is present, posted, telephone or online) and the parent /young person will be asked to complete a side-effects scale (Hill & Taylor, 2001). Patients who do not receive a diagnosis of ADHD or start medication within 3 months of baseline assessment will be asked to complete the SNAP-IV at 3 months.. ALL Parents are asked to complete the CSRI again at 3 months. ALL young people alongside their parents will also be asked to complete a EQ-5D-Y.

At 6 months after baseline assessment, all participants will be asked to complete the following measures: Parents will be asked to complete a SNAP-IV and CSRI and SDQ (Goodman, 1997) to assess changes in symptoms and symptom impact. Teachers will be asked to complete a SNAP-IV and SDQ. Young people alongside their parents are asked to complete a EQ-5D-Y. We ask families to complete the EQ-5D-Y collaboratively (between the child and parent/carer).

Participants are also be asked to complete a short questionnaire and/or take part in a short interview to gain their opinion on the acceptability/feasibility/utility of QbTest in routine NHS clinical practice.

Intervention Type
Other

Primary outcome measure
Number of clinic sessions until a confirmed correct diagnosis is achieved is measured using an appointment pro-forma from baseline to 6 months.

Secondary outcome measures
1. Time to diagnosis (in days) and the duration of visits (in minutes) are measured using an appointment pro-forma within 6-month time period
2. Clinician’s degree of confidence in their diagnostic decision is measured using a 6-point Likert scale (1 = definitely ADHD, 6 = definitely not ADHD) within a6 month time period
3. Stability in diagnosis is measured by asking clinicians to re-rate their diagnostic decision and confidence at 6 months
4. Diagnostic accuracy of QbTest by comparing diagnosis with diagnosis made through the ‘gold standard’ assessment (DAWBA) from baseline to 6 months
5. Quality of decision making is assessed through the side effects scale from baseline to 6 months
6. Treatment response is measured using the Strengths and Difficulties Questionnaire (SDQ), Children's Global Assessment Scale (CGAS) and the Swanson, Nolan and Pelham Teacher and Parent Rating Scale IV (SNAP-IV) at baseline, 3 and 6 months
7. Quality of life is measured using the EQ-5D-Y questionnaire at baseline, 3 and 6 months
8. Cost effectiveness of the QbTest is measured using the Client Service Receipt Inventory (CSRI) at baseline, 3 and 6 months
9. Opinions of the QbTest are measured using a specifically designed questionnaire or participant interviews at 6 months

Overall study start date
01/01/2014

Completion date
30/12/2016

Eligibility

Key inclusion criteria
1. Age 6-17 years (maximum 17 years at time of consent, may turn 18 during the study)
2. Referred for ADHD assessment
3. Capable of providing written informed consent (over 16)
4. Parental consent (under 16)

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 178; UK Sample Size: 178

Key exclusion criteria
1. Non-fluent in English
2. Suspected moderate or severe learning disability
3. Previous or current diagnosis of ADHD

Date of first enrolment
08/08/2014

Date of final enrolment
15/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottinghamshire Healthcare NHS Trust
Thorneywood CAMHS
160 Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Central Manchester University Hospitals NHS Foundation Trust
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

Medway NHS Foundation Trust
Medway Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
Leicestershire Partnership NHS Trust
Children and Young People’s services
Towers Hospital
Gipsy Lane
Leicester
United Kingdom
LE5 0TD

Study participating centre
United Lincolnshire Hospitals NHS Trust
Grantham and District Hospital
101 Manthorpe Road
Grantham
United Kingdom
LN2 4AX

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Children’s Hospital
E Prescot Road
Liverpool
United Kingdom
L14 5AB

Study participating centre
North East London NHS Foundation Trust
Havering CAMHS
Petits Lane
Romford
United Kingdom
RM1 4HP

Study participating centre

Nottingham University Hospitals NHS Trust
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Sussex Partnership NHS Foundation Trust
St Anne's Community Service Centre and CAMHS
Knightrider House
Worthing
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BN13 3EP

Sponsor information

Organisation
University of Nottingham

Sponsor details
Head of Research Grants and Contracts
Kings Meadow Campus
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United Kingdom
NG7 2NR

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Results from the study will be disseminated by publication in peer reviewed journals, conference presentation, publication on the CLAHRC East Midlands website and by submission to regulatory authorities. Publications will be written in first draft by the end of the 3 year study period (December 2017).
2. Study results will be fed-back via 'Bites', short, jargon free postcards which detail the main study findings. These will be made freely available to clinics. The study team also aim to publish short reports in local Trust magazines, such as 'Positive' within Nottinghamshire HealthCare Trust. A lay summary presentation will also be provided for interested clinics and Trusts and attend team meetings within Trusts to discuss our findings. The Qb forum will provide an additional avenue for dissemination.
3. Training on how to integrate QBTest into clinical practice will be provided by QbTech alongside some support from the EMAHSN and Health Education England, through hosting local seminars within each Trust, providing an opportunity for QbTest demonstrations, hands on experience and information on how best to utilise the QbTest to facilitate decision making in clinical practice. Training component to be specified – support from Qb.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/02/2017		Yes	No
HRA research summary			28/06/2023	No	No
Other publications		10/02/2017	18/08/2023	Yes	No
Other publications		19/06/2019	18/08/2023	Yes	No

Protocol article	01/12/2014	18/08/2023	Yes	No
Results article	26/04/2018	18/08/2023	Yes	No