

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

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| Submission date 04/07/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 04/07/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 18/08/2023 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> 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

Contact information

Type(s)

Scientific

Contact name

Dr Charlotte Hall

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 a 6 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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

17 years

Sex

All

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

United Kingdom

England

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

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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**

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E Prescott Road
Liverpool
United Kingdom
L14 5AB

Study participating centre**North East London NHS Foundation Trust**

Havering CAMHS
Petits Lane
Romford
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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
United Kingdom
BN13 3EP

Sponsor information

Organisation

University of Nottingham

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

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

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes