Feasibility trial to assess Attention Deficit Hyperactivity Disorder (ADHD) in the Criminal Justice System by using QbTest (a computer task)

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
09/01/2019		[X] Protocol		
Registration date 08/02/2019	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 10/11/2020	Condition category Mental and Behavioural Disorders	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Young people in prison are more likely to have Attention Deficit Hyperactivity Disorder (ADHD). To help decide if a young person has ADHD information from parents/teachers is helpful. Often this information is not available for young people in prison and therefore they miss getting the help they need. This means that some young people can be aggressive or experience a greater number of physical and mental health problems later in life. This study will try to identify young people with ADHD using a computer task called QbTest which does not need information from parents/teachers. This has not been tried before in prison with young people and we need to test out how we will go about using it by doing a small trial.

Who can participate?

Young people at HMPYOI Wetherby with ADHD symptoms

What does the study involve?

Part 1 of the study involves 60 young people from one prison. Half (30) are randomly selected to take the QbTest in addition to normal care, and 30 receive normal care alone. This will help to show if the larger trial can be done, how willing young people are to take part and how they feel about the study. In Part 2 young people and health professionals are interviewed to see what they think about QbTest and how it might be used in the real world. The researchers will work alongside patients and members of the public in the study to help decide how the study will be done and make sure the views of young people are fully included.

What are the possible benefits and risks of participating?

At the end of the study the researchers will write up their findings and decide if a large trial can be done. The larger trial could lead to better ways prisons can identify young people with ADHD and this could help more young people get the help they need. By participating, young people are helping to find out whether QbTest can reduce time to diagnosis for ADHD and they will also gain some experience of how psychological research studies are carried out. Participating

involves talking about health issues and some may find this upsetting. Some young people may find the QbTest procedure a bit uncomfortable as they have to wear a sensor on their head to track their head movements.

Where is the study run from? HMPYOI Wetherby (UK)

When is the study starting and how long is it expected to run for? November 2018 to November 2020

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

Who is the main contact?
Dr Charlotte Lennox
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

40004

Study information

Scientific Title

Using an objective computer task (QbTest) to aid the identification of Attention Deficit Hyperactivity Disorder (ADHD) in young people in the criminal justice secure estate: a feasibility randomised controlled trial

Acronym

FACT

Study objectives

To descriptively assess the feasibility and acceptability of the trial protocol.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wales REC 3, Health and Care Research Wales Castlebridge 4, 15 – 19 Cowbridge Road East, Cardiff CF11 9AB, Tel: 029 2078 5735, Email: corinne.scott@wales.nhs.uk, 02/12/2018, ref: 18 /WA/0347

Study design

Randomised; Interventional; Design type: Screening, Psychological & Behavioural

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

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

Health condition(s) or problem(s) studied

Learning disorders - ADHD

Interventions

QbTest (QbTech Ltd) is a computer task that measures three core aspects of ADHD: attention, impulsivity and motor activity. Performance on the task provides information (via an immediate report) on the three symptom domains of ADHD and a 'summary score' based on deviation from a normative data set based on age group and gender. QbTest can be used with individuals with mild to moderate learning disabilities as instructions on how to complete the task are visual. Practitioners use the information from the QbTest report in conjunction with the clinical

information (patient history, observation and ADHD symptom questionnaire) to inform their decision whether the young person has ADHD or not. The QbTest takes approximately 20 minutes to complete and the results will be discussed with the psychiatrist, this will take approximately 5 minutes.

Part 1 of the study will involve 60 young people from one prison. Half (30) will be randomly selected to QbTest in addition to normal care, and 30 to normal care alone. This will help the researchers to understand if the larger trial can be done, how willing young people are to take part and how they feel about the study.

In Part 2 the researchers will interview young people and health professionals to see what they think about QbTest and how it might be used in the real world. They will work alongside patients and members of the public in the study. They will help to decide how the study will be done and make sure the views of young people are fully included.

Intervention Type

Other

Primary outcome measure

- 1. Eligibility rate recorded as the number of eligible young people against the total number of young people identified with ADHD needs
- 2. Recruitment rate recorded as the number of eligible young people who consent to participate
- 3. Acceptability of randomisation recorded as the number of young people randomised
- 4. Attrition rate recorded as the number of young people who consent to participate that remain in the study until the end of follow up at 6 months

Secondary outcome measures

- 1. Behaviour is measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 3 and 6 months
- 2. ADHD symptoms are measured using the Barkley ADHD Rating Scale- IV Brief Screen (BAARS-IV Brief Screen) at baseline, 3 and 6 months
- 3. Health-related quality of life is measured using the Child Health Utility Instrument (CHU-9D) at baseline, 3 and 6 months
- 4. Objective rating of symptoms and functioning is measured by the Swanson, Nolan and Pelham Questionnaire (SNAP-IV) and Children's Global Assessment Scale (C-GAS) at baseline, 3 and 6 months
- 5. Number and duration of (in minutes) consultations/appointments until confirmed ADHD diagnosis as recorded on a pro-forma completed by clinicians after each consultation with the young person
- 6. Number of days until a confirmed diagnosis is reached using file information
- 7. Contact with services is measured using the modified Client Service Receipt Inventory (CSRI)) at baseline, 3 and 6 months
- 8. Number of reordered behavioural incidents and adjudications are collecting using prison file information at baseline, 3 and 6 months

Overall study start date

12/11/2018

Completion date

11/11/2020

Eligibility

Key inclusion criteria

Young people at HMPYOI Wetherby identified as presenting with ADHD symptoms via the CHAT e.g. any CHAT ADHD symptom read codes via SystmOne

Participant type(s)

Other

Age group

Child

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment

60

Key exclusion criteria

- 1. On remand (uncertain/sudden release)
- 2. Non English speaking
- 3. Previous or current confirmed diagnosis of ADHD
- 4. Currently receiving ADHD medication
- 5. Deemed to present too high a risk to either the researcher or the staff
- 6. Unable to provide informed consent (over 16)
- 7. Parental/legal guardian consent not received (under 16)

Date of first enrolment

11/02/2019

Date of final enrolment

02/03/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre HMPYOI Wetherby

York Rd

Sponsor information

Organisation

Pennine Care NHS Foundation Trust

Sponsor details

225 Old Street Ashton-under-Lyne England United Kingdom OL6 7SR +44 (0)161 716 3080 reagan.blyth@nhs.net

Sponsor type

Hospital/treatment centre

Website

https://www.penninecare.nhs.uk/research-projects/

ROR

https://ror.org/03t59pc95

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1216-20007

Results and Publications

Publication and dissemination plan

The trialists are planning on submitting the protocol for publication after registration.

Intention to publish date

11/11/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to the study involving prisoners.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/01/2020	10/11/2020	Yes	No
Results article		16/12/2022	22/03/2023	Yes	No
HRA research summary			28/06/2023	No	No