Evaluation of QbTest on a smartphone- A Clinical Investigation

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Ethical review	Approved WMO
Status	Pending
Health condition type	Developmental disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON53743

Source
ToetsingOnline

Brief title
QbMT - A CLINICAL INVESTIGATION

Condition

- Developmental disorders NEC

Synonym
ADHD, Attention-Deficit/Hyperactivity Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Qbtech
Source(s) of monetary or material Support: industry

Intervention

Keyword: ADHD diagnosis, ADHD test, QbTest, Smartphone application

Outcome measures

Primary outcome

The QbMT feasibility examination will involve as a primary objective, the examination of the data flow in the use of QbMT to identify potential errors or technical issues that may be associated with the data collection and QbTest parameter calculation. We will further examine the validity of QbMT in individuals diagnosed with ADHD. All the available QbTest measures of activity, impulsivity, and attention will be included as measures of interest in this study. These are described in the *Measures* section of the protocol.

Secondary outcome

The secondary objective of the QbMT study is to explore additional eye-movement variables and parameters that can be calculated from a mobile camera device and the mobile use of QbTest such as indices of activity, attention, and impulsivity, and compare this with individuals with and without ADHD.

Study description

Background summary

QbTest is a computer-administered test that objectively measures the three cardinal symptoms of Attention-Deficit/Hyperactivity Disorder (ADHD); inattention, hyperactivity, and impulsivity. The implementation of QbTest in the clinical setting has been shown to improve the efficiency, cost-effectiveness, and accuracy of the diagnostic process.
Recent reviews emphasize the need to further examine technology-based tools in the assessment and treatment evaluation of ADHD by objective monitoring and quantification of complex behavioural and cognitive processes in real-time.

Addressing this need to further improve the accuracy and objective identification of ADHD symptoms, a smartphone-based test, which incorporates QbTest, was developed (*QbMT` - Quantified behavioral Mobile Test).

Study objective

The objective of the current study is to evaluate QbTest on a smartphone (QbMT), in terms of:

1. The feasibility of QbMT as a smartphone software that incorporates the Quantified behavioral Test (QbTest *)
2. The validity of QbMT in individuals diagnosed with ADHD
3. The association between QbMT and QbTest parameters
4. An exploration of additional eye-movement parameters that could be used as indices of activity, attention, and impulsivity measures in QbMT for individuals with ADHD.

Study design

Non-interventional cross-sectional clinical study

Study burden and risks

This study has a low risk of causing adverse events to the participants and does not impact their clinical care and treatment. There are no significant hazards in the proposed study. A minor risk is that participants may experience some discomfort and boredom due to the length of the tests. The tests and tools implemented as part of this study are non-invasive and safe for the test taker. As the study involves the use of personal information, there is a slight risk of loss of confidentiality. Data will be collected, stored, and maintained according to the data protection regulations of the country in which the site is located.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

•Provide written informed consent (including parent/legally authorized representative (LAR) consent when this is required for individuals under 18 years old and assent as is required based on the age of participant) for QbMT;
•Aged > 6 years and < 60 years old;
•Referred for initial ADHD assessment;
•Have no prior diagnosis of ADHD;
•Have adequate sensory and physical ability to complete QbMT;
•Have not used psychostimulant medication for one month prior to test completion.

Exclusion criteria

•intellectual disability designated by IQ<75);
•a concurrent medical diagnosis that could significantly affect test performance (brain injuries, Parkinson*s disease, current epilepsy or active seizures, amyotrophic lateral sclerosis (ALS), multiple sclerosis, dementias (e.g., vascular dementia, Alzheimer disease, etc);
•other conditions that could affect test performance (migraine or other types of severe headache, chronic or acute pain);
•substance use (e.g., alcohol, drugs) that may affect performance on the day of

the test.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2022
Enrollment:	250
Type:	Anticipated

Medical products/devices used

Generic name:	QbMT (but device is not yet developed)
Registration:	No

Ethics review

Approved WMO

Date:	25-11-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	17-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL81608.000.22