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Can we identify young people and adults who may benefit from methylphenidate, the most common medication for ADHD, from their initial response to a single test dose rather than after several weeks of daily treatment?

Submission date
23/06/2026

Recruitment status
Enrolling by Invitation

Registration date
18/08/2026

Overall study status
Ongoing

Last Edited
18/08/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Attention-deficit/hyperactivity disorder (ADHD) is very common, and people with ADHD often wait years to start treatment. Once they start, it can take months to find the right medication for them. Stimulant medications, such as methylphenidate (MPH), are generally effective, but response may vary from person to person. MPH is often given first, and patients need to take it every day for several weeks before a clinician can tell if it is right for them. If MPH does not work, clinicians will try other medicines, one by one. This approach is expensive and delays getting the right treatment. Without the right treatment, people with ADHD have higher chances to do poorly in school or work. With this study, we want to understand if MPH is the right medicine for a person with ADHD or if they need another one faster.

Who can participate?

We are currently recruiting young people and adults (aged 12 to 64 years) from existing ADHD waiting lists at participating NHS Trusts only (Hampshire and Isle of Wight Healthcare NHS Foundation Trust and South London and Maudsley NHS Foundation Trust).
IMPORTANT: Please note that we will not be able to recruit participants from other NHS Trusts or via any website.

What does the study involve?

Participants will complete clinical questionnaires, cognitive tasks measuring skills such as attention, and physiological measures such as pulse under MPH and under placebo over two separate days. They will then start standard treatment with MPH. We will follow them up at 2 and 6 months.

What are the possible benefits and risks of participating?

Eligible participants will be started on standard ADHD treatment. Since there are currently very

long waiting lists for ADHD treatment, this might mean that participants could start treatment earlier.
During the initial two-month treatment with MPH, our research team will also provide regular check-ins (e.g., via phone call) additional to standard care to see how participants are doing.
Participating in this study will improve our understanding of ADHD treatment. While it may not bring participants a direct clinical benefit, this may help improve care for other people with ADHD in the future.
Those who choose to participate in this study will be compensated for their time. They will receive £50 at the completion of the 2-month follow-up and £30 at the completion of the 6-month follow-up. Travel expenses for the two experimental visits will be reimbursed up to £20 per participant.
Medication for ADHD, including the initial dose administered when we do the tests, could have side effects. These are usually mild, like headaches, stomach aches, and mild increases in pulse and blood pressure. To reduce risks, medication will be prescribed and monitored by one of our NHS clinicians. During the study, participants will be asked to swallow small capsules. Therefore, we will ask participants if they can safely swallow small capsules.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
August 2026 to August 2028

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

Who is the main contact?
Dr Valeria Parlatini

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
344657

Central Portfolio Management System (CPMS)
62715

National Institute for Health and Care Research (NIHR)
305518

Study information

Scientific Title
The first test dose to predict longer-term treatment response in attention-deficit/hyperactivity disorder: Combined Approach to Response Evaluation in ADHD v.1 (CARE-ADHD)

Acronym
CARE-ADHD

Study objectives
We will investigate whether acute changes in clinical, cognitive and/or physiological measures under a single MPH dose predict symptom improvement at 2 months.

We hypothesise that an acute change in clinical, cognitive, and/or physiological measures under a single dose of MPH, combined with clinical and demographic characteristics, will predict symptom improvement after 2-month standard treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/06/2026, South Central - Hampshire A Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; hampshirea.rec@hra.nhs), ref: 26/SC/0160

Primary study design
Interventional

Study design
Basic science study with human participants

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention-deficit/hyperactivity disorder (ADHD)

Interventions
Participants will complete clinical scales; cognitive tests measuring skills such as attention and memory; and physiological measures such as pulse, once under a single dose of methylphenidate (15 mg for young people and 20 mg for adults), and once under a single dose of placebo before

starting standard treatment with methylphenidate, a first-line medication for both young people and adults with ADHD. We will measure treatment response at 2 months and follow them up naturalistically at 6 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylphenidate

Primary outcome(s)
Difference in total ADHD symptoms and underlying domains (inattentive and hyperactivity-impulsivity symptoms) after 2 months of standard MPH treatment (follow-up 1) as compared to pre-treatment. ADHD symptoms will be measured with the following ADHD symptom rating scales:

Investigator-rated:
1. ADHD Rating Scale (ADHD-RS) (adolescents)
2. Adult ADHD Investigator Symptom Rating Scale (AISRS) (adults)

Parent-rated:
1. ADHD Rating Scale Version 5 (ADHD-RS-5) (adolescents)

Self-rated:
1. Barkley Adult ADHD Rating Scale-IV (BAARS-IV) (adults)
2. Adult ADHD Self-Report Scale (ASRS) v1.1 (validated in adolescents)

Timepoint(s): Follow-up 1 (2 months)

Key secondary outcome(s)
1. Other treatment outcomes at 2 months:
1.1. Treatment response categorically defined
1.2. Overall clinical severity measured using Clinical Global Impressions (CGI)
1.3. Quantitative behaviour (Qb) test
1.4. Physiological measures such as pulse
1.5. Adverse effects measured using Hill and Taylor/Canadian ADHD Resource Alliance (CADDRA)
1.6. Quality of life/functioning measured using EuroQol and Child Health Utility 9 Dimensions (CHUD-9) and Weiss Functional Impairment Rating Scale (WFIRS)
2. Treatment outcomes at 6 months:
2.1. ADHD symptoms measured using ADHD symptom rating scales listed in primary outcomes
2.2. Overall clinical severity measured using Clinical Global Impressions (CGI)
2.3. Adverse effects measured using Hill and Taylor/Canadian ADHD Resource Alliance (CADDRA)
2.4. Quality of life/functioning measured using EuroQol and Child Health Utility 9 Dimensions (CHUD-9) and Weiss Functional Impairment Rating Scale (WFIRS)
3. Change in medication and clinical attendance/dropouts recorded at 6 months

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Age >=12 and <=64 years
2. Clinical diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) confirmed according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR). Participants will be mainly recruited from treatment waiting lists but new referrals will also be invited, and assessments carried out as per standard practice and according to DSM-5-TR criteria
3. No prior treatment with methylphenidate (MPH) for at least 1 year
4. Willing to start treatment with MPH
5. Participants will be included only if they (or their parents, if participant is below 16 years old) have capacity to give informed consent, in addition to assent if participant is below 16 years old
6. Able to swallow small capsules (single dose testing)
7. Able to complete the computer-based tasks used in this study
8. Currently on waiting list for starting ADHD treatment (or assessment and treatment)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. No conditions for which MPH or participation would be considered inappropriate according to the treating clinician (e.g., contraindications to treatment or crisis presentations)
2. No concurrent pregnancy or pregnancy-planning or lactation
3. No concurrent psychopharmacological treatment, except for melatonin, promethazine and sleeping tablets to avoid confounding during single-dose testing
4. Individuals not able to understand and follow instructions to complete the computer-based and other tasks involved in this study and/or to provide valid consent/assent

Date of first enrolment
21/08/2026

Date of final enrolment
20/08/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hampshire and Isle of Wight Healthcare NHS Foundation Trust
Tatchbury Mount Hospital
Calmore
Southampton
England
SO40 2RZ

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Study participating centre
University of Southampton
University Road
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England
SO17 1BJ

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
The datasets generated during and/or analysed during the current study will be available upon request from the study chief investigator, Valeria Parlatini (hiowh.careadhd.study@nhs.net). Specifically, prior to completion of the analyses and deposition in the repository, bona fide researchers may request access to pseudonymised data. Requests will be reviewed by the chief investigator and study management group to ensure that data sharing is appropriate, supports the generation of new knowledge, and does not compromise ongoing analyses. Appropriate safeguards will be applied to ensure the integrity, confidentiality, and responsible use of the data. Where access is granted, data sharing will be subject to a data use agreement if appropriate. The data use agreement must detail agreed use and appropriate management of the research data to be shared. Studies shall promote appropriate acknowledgement of the significant contributions of all parties to creating new value through data-sharing, including the researchers who generated the data and the original funder. Prior to publishing, appropriate measures must be in place to ensure that Foreground IP, Arising Know How and Research Data are adequately protected. This includes, but is not limited to, applying for registration of Intellectual Property if appropriate and ensuring that the proposed publication does not contain any commercially sensitive information. Data sharing procedures are in line with the study's Participant Information Sheets and Consent Forms.

IPD sharing plan summary
Available on request