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Personalising ADHD medication treatment for children and young people

Submission date
31/07/2026

Recruitment status
Recruiting

Registration date
14/08/2026

Overall study status
Ongoing

Last Edited
14/08/2026

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 a common condition that affects children's behaviour, attention and activity levels. Medicines can be an effective treatment for ADHD, but it is often difficult to know which medicine will work best for a particular child. As a result, some children may need to try several medicines before finding one that is effective and well tolerated.
This study aims to test a new online decision-support system called PETRA. The system is designed to help children, parents or carers, and doctors make shared decisions about ADHD medication. The study will assess whether it is practical and acceptable to run a larger clinical trial comparing this personalised approach with standard care.

Who can participate?
Children and young people aged 6 to 17 years with a clinical diagnosis of ADHD who are waiting to start medication treatment may be eligible to take part. A parent or carer with parental responsibility must also participate, be able to give informed consent, have access to the internet and email, and be able to understand English well enough to use the study materials.

What does the study involve?
Parents or carers will be invited to visit the study website, where they will complete screening questions and provide consent if they wish to take part. They will also provide information about their child's health and complete questionnaires about quality of life, ADHD symptoms, side effects and related conditions.
Participants will be randomly allocated to one of three groups. One group will use the personalised PETRA decision-support system, one group will use a best-evidence version of the system without personalisation, and one group will receive usual care without a decision-support tool.
Participants will attend their normal medication appointment, where routine clinical information such as height, weight, blood pressure and pulse will be collected. The doctor will then prescribe ADHD medication.
After starting treatment, parents or carers will complete a short daily online question about medication use. They will also receive telephone calls from a research assistant approximately every four weeks to discuss medication use, adherence and any side effects.

Follow-up assessments will take place at approximately 12 weeks and 24 weeks. These will include routine clinical measurements, medication reviews and questionnaires about quality of life, ADHD symptoms and medication side effects. Some participants may also be invited to take part in an interview about their experiences of the study.

What are the possible benefits and risks of participating?
Participants allocated to one of the decision-support groups may benefit from using a tool designed to help identify the most suitable ADHD medication. This may help reduce the need to switch medications and may reduce unwanted side effects. All participants will also receive a detailed assessment of possible additional mental health conditions through study questionnaires.
The study is considered low risk. The main burden is the time required to complete questionnaires, answer a daily adherence question and take part in telephone follow-up calls, which are expected to last about 15 minutes every four weeks.

Where is the study run from?
The study is run from the University of Southampton Clinical Trials Unit and will recruit participants through one NHS Trust with two participating hospitals in England.

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

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

Who is the main contact?
petra@soton.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Integrated Research Application System (IRAS)
369722

Central Portfolio Management System (CPMS)
73351

National Institute for Health and Care Research (NIHR)
303122

Study information

Scientific Title
PErsonalising the pharmacological TReatment of Attention deficit hyperactivity disorder (ADHD) in children

Acronym
PETRA

Study objectives
Primary objective:
To determine the feasibility of running a randomised controlled trial comparing a decision-support system to usual care

Secondary objectives:
1. To assess acceptability of using a tool to support medication choices
2. To review contamination between trial arms

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 30/07/2026, London – Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; fulham.rec@hra.nhs.uk), ref: 26/LO/0599

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose

Treatment

Study type(s)

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

Interventions
There will be one participating NHS Trust, with two different hospitals recruiting suitable patients into the study.
Potentially suitable patients will be identified from the ADHD medication waiting list. Primary caregivers of children aged 6 to 17 years will be invited to take part by clinicians and research assistants. They will be sent a summary information sheet that will direct them to the study website, where they can read a full patient information sheet and learn more about what the study involves.

Participants will have the contact details of a research team member to ask any questions they might have before consenting.

Caregivers will complete initial screening questions on the study website. They will then complete informed consent on the study website and add information about their child's medical history and demographics. This is followed by a quality of life questionnaire for themselves (EQ-5D-5L), and two quality of life questionnaires for the child (EQ-5D-5L and CHU9D). They will also complete the ADHD rating scale on the website, the Hill and Taylor Side Effects Scale, and the DAWBA to assess comorbidities.

They will then be split into three groups: 34 will use the personalised internet-based system to inform ADHD medication discussions (PETRA), 34 will use the best-evidence website, and 34 will discuss medication with their doctor without the use of a decision support system, as is standard practice. The groups using the PETRA website or the best-evidence website will be blinded to the exact group they are in. They will be aware that they are in the intervention group, but the website will look the same for each group.

This design has been deemed necessary to:
• Help ensure the positive effects of the tool are from personalisation and not derived simply from using a decision support tool for shared decision-making
• Limit the possibility of contamination of the prescriber, who may observe different recommendations for patients with similar clinical profiles, as one may be assigned to the personalised arm and another to the best-evidence arm

They will then attend their medication appointment, where they will complete their baseline investigations and receive their prescription for ADHD medication.

At this appointment, the following activities will occur:
• Confirm the child is eligible
• Measure height, weight, blood pressure, and pulse
• Collect information on any other medications the participant is taking
• Complete the ADHD rating scale again with the researcher if required, or the researcher will check the responses to the parent-completed scale
• Collect information regarding health, social care, and community services used by the participant
• Prescribe the child's medication, either using a decision support system or not

Qualitative interviews will take place shortly after the first appointment, if the participant chooses to take part.

Once the participant has collected their prescription and their child has started taking their medication, they will need to complete a daily adherence question online.

For the full duration of the study, the participant will also receive regular four-weekly calls from the research assistant to discuss their child's ADHD medication and provide any adjustments, as well as collect adherence and side effect data.

The participant will attend the hospital for a follow-up visit as part of standard care, and the following will be conducted as close to 12 weeks as possible.

The data collected will include:
• Height, weight, blood pressure, and pulse
• Other regular medications
• How much of the prescribed medication has been taken

At 12 weeks, participants will complete the following online questionnaires:
• Quality of life questionnaires (two for the child and one for the parent/carer)
• Hill and Taylor Side Effects Scale

During the four-weekly calls, close to 12 weeks:
• Collect information regarding health, social care, and community services used by the participant
• Complete the ADHD symptom rating scale

Between the 12-week and 24-week visits, the researcher will contact the participant at four-weekly intervals to collect information on any changes to the medication prescription and to discuss medication adherence and side effects.
The participant will attend the hospital for a follow-up visit as part of standard care, and the following will be conducted as close to 24 weeks as possible.

The data collected will include:
• Height, weight, blood pressure, and pulse
• Other regular medications
• How much of the prescribed medication has been taken

At 24 weeks, participants will complete the following online questionnaires:
• Quality of life questionnaires (two for the child and one for the parent/carer)
• Hill and Taylor Side Effects Scale

During the four-weekly calls, close to 24 weeks:
• Collect information regarding health, social care, and community services used by the participant
• Complete the ADHD symptom rating scale

Intervention Type
Other

Primary outcome(s)

Feasibility assessed by:
1. Acceptability and experience of ADHD medication decision-making and study participation measured using a qualitative interview shortly after the first medication appointment
2. Recruitment rate (randomised out of those approached) measured using trial database at the end of study
3. Withdrawal rates measured using trial database at the end of study
4. Data completeness of the outcomes below measured using trial database at end of study

Key secondary outcome(s)
1. Medication adherence measured using a daily online adherence question daily from initiation of ADHD medication until 24 weeks
2. Medication adherence measured using research assistant four-weekly telephone follow-up calls at 4, 8, 12, 16, 20 and 24 weeks
3. ADHD medication side effects measured using research assistant four-weekly telephone follow-up calls at 4, 8, 12, 16, 20 and 24 weeks
4. Height measured using hospital clinic assessment at 12 and 24 weeks
5. Weight measured using hospital clinic assessment at 12 and 24 weeks
6. Blood pressure measured using hospital clinic assessment at 12 and 24 weeks
7. Pulse measured using hospital clinic assessment at 12 and 24 weeks
8. Concomitant medication use measured using medication review at hospital follow-up visits at 12 and 24 weeks
9. Prescribed ADHD medication taken measured using medication adherence assessment at hospital follow-up visits at 12 and 24 weeks
10. Child health-related quality of life measured using the EQ-5D-5L questionnaire at 12 and 24 weeks
11. Child health-related quality of life measured using the CHU9D questionnaire at 12 and 24 weeks
12. Parent/carer health-related quality of life measured using the EQ-5D-5L questionnaire at 12 and 24 weeks
13. ADHD medication side effects measured using the Hill and Taylor Side Effects Scale at 12 and 24 weeks
14. Health, social care and community service use measured using research assistant four-weekly telephone follow-up calls at 12 and 24 weeks
15. ADHD symptom severity measured using the ADHD symptom rating scale at 12 and 24 weeks
16. Changes to ADHD medication prescription measured using research assistant four-weekly telephone follow-up calls at 16, 20 and 24 weeks

Completion date
30/11/2028

Eligibility

Key inclusion criteria
Children/adolescents:
1. Aged 6-17 years
2. With a clinical diagnosis of ADHD by a clinical team (using either DSM-5-TR or ICD-11 criteria)
3. On the waiting list for the pharmacological treatement of ADHD

Inclusion criteria for parent/carer:
4. Parental responsibility
5. Knowledge of child’s medical history sufficient to complete assessments.

6. Access to internet and email
7. Able to give valid informed consent
8. Sufficient understanding of English to allow access/understanding of the PETRA decision-support system and study documentation

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Based on the clinical judgement of the prescribing clinician, any current condition that would be a contraindication for ADHD medication, including abnormal cardiovascular examination (i.e., BP>95th percentile (for stimulants) and low blood pressure for guanfacine/clonidine as well as tachycardia) or any conditions that should be treated before starting pharmacological treatment for ADHD such as alcohol/substance dependence, active psychosis, and active mania
2. Immediate risk to self or others

Date of first enrolment
01/09/2026

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
-

-
England
-

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

IPD sharing plan summary
Not expected to be made available