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Testing a nature-based parent program for children with attention deficit hyperactivity disorder

Submission date
03/11/2025

Recruitment status
Recruiting

Registration date
04/11/2025

Overall study status
Ongoing

Last Edited
21/01/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Waiting lists to access ADHD support are long. Lack of support for children leads to mental health difficulties for both children and their families. Spending more time outside and in nature can help children with ADHD.
We created a nature-based activity box to be used at home by children and their families. We created this with children with ADHD, their families and staff that support them. It is designed to support ADHD symptoms and improve quality of life. The box includes activities to support time in nature. It is for use with usual care (medication) after being told that your child has an ADHD diagnosis.
We want to find out if a nature-based activity box (CONIFAS V1) can be used and accepted in NHS Attention Deficit Hyperactivity (ADHD) services.

Who can participate?
Children aged 6-11 years on a waiting list for ADHD support post-diagnosis and their families

What does the study involve?
We want to find out if the nature-based activity box can be used and accepted in NHS ADHD services. We also want to find out if the activity box can be tested using a particular research method called a randomised controlled trial. This will help us find out if we can test to see if the activity box helps with ADHD symptoms and quality of life. All children and families will get usual care but half will also get the activity box. This is how we will see if the research method (randomised controlled trial) can be tested. At the end, those that did not get the activity box will get a nature-based goodie bag. We will ask children, their families and staff what they think about the activity box.

What are the possible benefits and risks of participating?
Taking part in this study is very low risk. Both groups will be asked to complete some questionnaires about their child's well-being and activities. We will support parents/carers to complete the questionnaires if required.
If a child receives a nature activity box, the activities are designed to be safe and suitable for

children, but we still ask that an adult supervises them during the activities to make sure they stay safe.
We cannot guarantee any direct benefit from taking part. However, families who receive the nature activity box may find the activities enjoyable and helpful for spending time outdoors together. Families who do not receive the nature activity box will still receive a nature goodie bag at the end of the study so they can also try the activities.
By taking part, individuals will be helping researchers learn more about how nature-based activities and clinician support can affect children's wellbeing.

Where is the study run from?
Humber Teaching NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2025 to January 2027

Who is funding the study?
NIHR Research for Patient Benefit (UK)

Who is the main contact?
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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
346379

Protocol serial number
NIHR207869, CPMS 63496

Study information

Scientific Title
CO-produced Nature-based Intervention Feasibility for children with attention deficit hyperactivity disorder Study

Acronym
CONIFAS2

Study objectives
The overarching aims are to assess if the delivery of the CONIFAS intervention is feasible and acceptable to children with attention deficit hyperactivity disorder (ADHD), their families, and NHS neurodiversity professionals, and to test the feasibility of conducting a randomised controlled trial when compared to treatment as usual.

The objectives are to address uncertainties regarding:
1. Feasibility and acceptability of trial processes related to recruitment, randomisation, and collecting health/wellbeing, process, and health economic outcomes.

2. Feasibility and acceptability of delivering the CONIFAS intervention in neurodiversity services, including children and young people's (CYP) experiences of receiving and staff experiences of delivering the intervention.
3. How the intervention is embedded into practice to understand how context affects implementation and outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/11/2025, East Midlands - Derby Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 (0)207 1048 154; derby.rec@hra.nhs.uk), ref: 25/EM /0224

Study design
Multi-centre randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

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

Interventions
This is a multi-centre, randomised controlled feasibility trial comparing the CONIFAS intervention to 'Treatment As Usual' (TAU) when provided to families on the post-diagnosis ADHD support pathway. TAU is defined as the current provision of the site from which participants are recruited. This will be recorded throughout the study. The study also includes a feasibility health economics evaluation and a process evaluation. Participants will be expected to take part in the study for a total of 6 weeks.

Rationale:
The CONIFAS nature-based intervention was co-produced as an intervention to support children with ADHD and their families to engage with nature to improve quality of life and reduce ADHD symptoms. It is a home-based, family-led intervention with support from a professional and optional peer support.

Materials:
The activity box element of the intervention is presented in a portable box and includes:
1. 47 laminated '10-minute challenge' activity cards, colour coded by seven categories (rules and boundaries, active, body and senses, creative, discovering, relaxing, and exploring)
2. 36 'Can you find something' cards
3. A psychoeducation booklet for parents / guardians
4. A psychoeducation and activity booklet for children. The intervention box also includes a mini torch, modelling clay, a wood 'cookie' to draw or paint on, and a daily challenge calendar with nature stickers.

Procedures:
The intervention box will be provided to families randomised to the intervention either face-to-face or via the post. Once the box has been received, a neurodiversity ADHD service clinician will provide an initial introduction to the intervention (psychoeducation and practical advice), most likely via telephone or video call, and then a fortnightly support call (three in total over the 6-week intervention period) for encouragement and problem solving. Two videos are available to support families' introduction to the intervention, as well as QR codes for audio recordings of written text. Supporting documentation for the fortnightly calls was developed with a PPIE group and stakeholders. Families of participants randomised to the intervention group will also have the option of joining a community of experience forum for additional peer support.

Setting:
The intervention will be carried out in local green spaces around the children and families' homes, for example in gardens and parks, though they are also welcome to access nature spaces further afield. Families are encouraged to access nature for ten minutes every day. This can be done anywhere that is available to them, there is no need to travel far to access countryside, etc. Some of the nature activities can be done inside the home whilst using nature (e.g. nature listening through an open window).
Delivery will take place over 6 weeks with families encouraged to undertake at least 10 minutes of daily nature engagement in whatever way they would like to each day. The 10-minute dose of nature was designed to be a practical and achievable time for parents to spend time each day outdoors.

Tailoring:
The CONIFAS intervention has been developed with accessibility in mind. During co-production, it was considered how families who live in apartments with reduced access to green space or those living in more urban areas can benefit from the intervention. There are a number of activities which take place in the home using natural materials or which do not need significant resources (e.g. cloud watching, listening to birds). Psychoeducational components of the intervention provide an understanding of the evidence base for parents/guardians including the fact that small 'micro-activities' in nature can be beneficial for wellbeing.

Control/Comparator:
All participants will continue to receive Treatment as Usual (TAU) according to their current site provision. The components of TAU will be recorded for each individual participant and whether this changes over the course of the study. Current commissioning for both services is to be placed on a waiting list with crisis management as required. No medication is prescribed until children have received a medical assessment. Should the services change their treatment pathways, discussion will be had with sites about how CONIFAS can continue to fit as part of a wider intervention pathway, and any changes in participant care will be recorded. At the end of the study the control group will receive a nature-themed goodie bag which will include elements of the intervention, i.e. activity cards and starter activities.

A web-based randomisation system will be provided by Hull Health Trials Unit (HHTU), within a commercial web-based system, REDCap Cloud (RCC). Participants will be randomised in a 1:1 ratio using random permuted blocks to study arm (i) CONIFAS intervention, or study arm (ii) TAU, stratified by site.

Semi-structured qualitative interviews will be undertaken with family dyads receiving the intervention from each site (parents/guardians and/or their child/ren), and families recruited to the control arm (n = 12-15). The length of interviews will be between 30-60 minutes. Purposive sampling will focus on collecting data from those who complete the intervention, and those that

withdraw. Interviews will be conducted in person (at an agreed location) or online, depending on the preference of the interviewee. A small sample of older children will be interviewed alone, with parental agreement. Interviews will be undertaken by researchers with experience of working with this age group.

Online/phone interviews with staff (n = 4-5) will explore delivery of the intervention and study, as well as discuss implementation issues. A convenience sample of staff involved in study delivery will be recruited.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes:
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by January 2027 (number of eligible young people, number approached, number of exclusions due to non-English speaking families, what are the common languages and how can participation be enabled in a larger study)
2. Retention rate recorded by withdrawal rates from the study up to January 2027
3. Demographics of participants recorded at baseline and 6 week follow up to see whether it is possible to recruit a diverse sample, and can balance be achieved across trial arms
4. Data completeness recorded as percent of parents and children completing the outcome measures at baseline and 6 week follow up
Recording for missing data, completion rates, differential completion between arms
5. Fidelity to the intervention recorded using questionnaires at 6 week follow up to understand can the intervention be delivered with fidelity by NHS staff
6. Acceptability assessed qualitatively through semi-structured interviews after the 6 week follow up to understand whether the intervention and an RCT design are acceptable from the perspective of families, children, and staff
7. Adherence to intervention assessed using questionnaires and semi-structured interviews after the 6 week follow up to see whether children and parents/guardians engage with the intervention

We will also evaluate whether the following continuation criteria have been met, prior to planning a future definitive trial:
1. Site set-up is fully achieved for two sites including site approvals obtained, staff trained to deliver intervention, open to recruitment (site greenlight) by December 2025.
2. Data completion rates of CHU9D (candidate primary outcome) at baseline and 6 weeks are at 60% or higher
3. No major concerns are identified in the delivery of the intervention or RCT by the study end (January 2027)
4. Aim to recruit 84 participants across two sites over 9 months with 3+ recruited per month
5. >75% of core intervention components delivered at end of final participant follow up (estimated November 2026)
6. Engagement/adherence with the intervention >80% of intervention tasks completed at end of final participant follow up (estimated November 2026)

Key secondary outcome(s))
Feasibility of collection of the following measures:
1. Symptoms of attention-deficit/hyperactivity disorder measured using the Swanson, Nolan, and Pelham (SNAP-IV) scale at baseline and 6-week follow up.

2. Symptoms of anxiety and depression in children and adolescents measured using the Revised Children's Anxiety and Depression Scale (RCADS) at baseline and 6-week follow up.
3. How connected children are to the natural world measured using Nature Connection Index (NCI) at baseline and 6-week follow up
4. Bespoke acceptability and accessibility measures measured using scaled questions at 6-week follow up
5. Bespoke fidelity checklist (clinician-completed) at 6-week follow up
6. Anonymous parent-completed adherence questionnaire at 6-week follow up
7. Intervention daily diary sheet used daily by parents during the 6-week intervention period

Completion date
30/01/2027

Eligibility

Key inclusion criteria
Children:
1. Aged 6-11 years
2. on a waiting list for ADHD support post-diagnosis
3. Have sufficient understanding of English to participate in the study
4. Have parent(s) / guardian(s) with sufficient understanding of English to participate in the study

Parents/guardians:
1. Parent/guardian for a child study participant
2. Has sufficient understanding of English to participate in the study
3. Is willing and able to complete the study outcome measures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
11 years

Sex
All

Total final enrolment
0

Key exclusion criteria

Children:
1. Pose a risk of harm to self or others
2. Have profound additional difficulties as determined by parent(s)/guardian(s)

Parents/guardians:
1. Unwilling or unable to consent or complete the study outcome measures

Date of first enrolment
26/01/2026

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq Block a Willerby Hill
Beverley Road
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Hull
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HU10 6ED

Study participating centre
Navigo Health and Social Care CIC
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Sponsor information

Organisation
Humber Teaching NHS Foundation Trust

ROR
https://ror.org/016bnqk64

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
Anonymised participant data will be made available on request following consideration by the study team on a case-by-case basis. Requests should be made to the CI Dr Hannah Armitt (hannah.armitt@nhs.net) and will be considered by the TMG. Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor or its designee. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	29/10/2025	19/12/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes