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Co-producing a nature activity for children with ADHD

Submission date
05/04/2022

Recruitment status
No longer recruiting

Registration date
17/05/2022

Overall study status
Completed

Last Edited
09/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Children with Attention Deficit Hyperactivity Disorder (ADHD) can be creative and energetic and can sometimes struggle with attention and controlling behaviour. Early support with these can be helpful for mental wellbeing, relationships, educational and working opportunities. Engaging with nature has been shown to help with some characteristics of ADHD and to have a positive impact on children's mental health. Waiting lists to access support for ADHD are often long, leaving children and families unsupported. Government health policy is increasingly focusing on prescribing 'green treatment' options like swimming, running, cycling, and using outdoor learning in schools to increase engagement with green spaces. These are not yet specifically tailored to children with ADHD, however. The CONIFAS research study is funded by the National Institute for Health Research's (NIHR) Research for Patient Benefit (RfPB) funding stream. It is run by the Humber Teaching Hospitals NHS Foundation Trust, the University of York, the COMIC research team, and the Leeds and York Partnership NHS Foundation Trust. It will be run in partnership and with support from the Yorkshire Wildlife Trust, the ADHD Foundation, and patient and public involvement (PPI). The study aims to work with children and their families and professionals from the NHS, charities, and other organisations to create a nature-based intervention for children with ADHD and their families to help with some of the typical characteristics of ADHD.

Who can participate?
In the co-production phases: children aged between 5-11 years with a diagnosis of ADHD, their parent/guardian, and any professional working in health care or the third sector with experience of working with children with ADHD and/or nature-based activities/interventions.
In the user-testing phase: children aged between 5-11 years with a diagnosis of ADHD and their parent/guardian

What does the study involve?
The study involves the co-production of a nature activity for children with ADHD and user testing of this intervention by children and families with lived experience of ADHD. There are four phases: phase 1 involves three 'discovery' sessions (one with 10 children with ADHD and their parent/guardian, one with just these 10 parents/guardians, and one with 10 professionals) where the researchers will discuss nature-based interventions for children with ADHD and any

barriers and solutions engaging with nature for these children. Phase 2 involves four coproduction workshops with the same participants as the discovery phase (one with 10 children with ADHD and their parent/guardian, one with just these parents/guardians, one with 10 professionals, and one with everyone together) where the researchers will look at different activities and come up with what the nature-based intervention should be based on discussions from the discovery phase. Phase 3 is the user-testing phase and involves recruiting 10 further children with ADHD and their parent/guardian to test the intervention and complete the pre- and post-measures. The intervention will be tested for 6 weeks. Follow-up will be after this six week period. Phase 4 is the refine phase where the co-production participants meet again and refine the intervention based on information gathered during user testing.

What are the possible benefits and risks of participating?
Taking part in this study offers the opportunity to contribute to the creation of a nature-based intervention for children and young people with ADHD. Participants will be able to share ideas, thoughts, and experiences about this along with other families and professionals. This study may also inform health and education professionals who may help children and young people in the future. Participants will receive a shopping voucher for their participation. The study team do not foresee any risks to participation, however, as the intervention is nature-based, the discovery and co-design groups will be held at a nature reserve. Typical risks associated with being outdoors apply.

Where is the study run from?
The study is run from the COMIC research team office and the University of York (UK). All discovery and co-design groups (except the parent/guardian only sessions) will be held in person at Barlow Common, a Yorkshire Wildlife Trust nature reserve near Selby. The parent/guardian only sessions will be virtual.
The user-testing phase is done from participant homes and preferred outdoor locations.

When is the study starting and how long is it expected to run for?
March 2022 to August 2023

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

Who is the main contact?
Ellen Kingsley
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315214

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR203043, IRAS 315214, CPMS 52634

Study information

Scientific Title
CO-production of a Nature-based Intervention For children with ADHD

Acronym
CONIFAS

Study objectives
Current study hypothesis as of 16/12/2022:

The study aims to co-produce a nature-based intervention for children and young people with Attention Deficit Hyperactivity Disorder (ADHD) with children, families, and professionals with lived experience of ADHD. It also aims to test the intervention with children and families with lived experience of ADHD and to use their feedback to refine the intervention.

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Previous study hypothesis:

The study aims to co-design a nature-based intervention for children and young people with Attention Deficit Hyperactivity Disorder (ADHD) with children, families, and professionals with lived experience of ADHD. It also aims to test the intervention with children and families with lived experience of ADHD and to use their feedback to refine the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Co-production phases approved 23/05/2022, University of York Department of Environment and Geography Research Ethics Committee (University of York, Wentworth Way, York, YO10 5NG, UK; +44 (0)1904 322999; environment@york.ac.uk). User-testing phase approved 09/12/2022 by the same committee.

Study design
Co-production trial with a non-randomized user-testing phase

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied

Attention Deficit Hyperactivity Disorder (ADHD)

Interventions

Current interventions as of 16/12/2022:

The study consists of four phases. In the first phase, three groups with children with ADHD and their family members, professionals from mental health, wildlife charities and researchers will meet for discovery workshops involving creative activities to consider how nature-based interventions may be used and what aspects of support for ADHD are needed. In phase 2 workshops will develop the intervention based on the information gathered in phase 1. In phase 3 a different group of children and families will test the intervention and provide outcomes before and after (including ADHD and mental health symptom measures). Phase 4 will use feedback from the user testing in phase 3 to further improve the intervention.

The overall aim of the intervention is to educate families on the benefits of interacting with nature and to support them to do so at their own pace, starting from any level of experience, by building up confidence in nature. The intervention is to be self-led by families with support from the researchers at this stage of development in the form of regular contact with the research team via phone calls to support motivation and problem solving. The intervention materials are offered in a bespoke CONIFAS box which includes:

- 'This box includes…' instruction sheet
- 'Can you find something…' cards for introduction activity
- Parent/guardian education booklet
- Child education booklet
- Activity cards set
- Daily challenge calendar

Support for the use of this intervention will be provided via 'check-in' phone calls with the study RA or TC every two weeks. This time will be used to discuss anything participants would like to raise regarding the intervention. A final 'check-in' phone call will also be offered at the end of study participation following outcome measure completion.

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Previous interventions:

The intervention will be based on the Five Ways to Wellbeing (Connect, Be Active, Take Notice, Learn and Give), an evidence-based health campaign. It will be developed with participants and staff from the Yorkshire Wildlife Trust who have experience of developing large nature-based campaigns as well working with parents/guardians, young people, and professionals.

The study consists of four phases. In the first phase, three groups with children with ADHD and their family members, professionals from mental health, wildlife charities and researchers will meet for discovery workshops involving creative activities to consider how nature-based interventions may be used and what aspects of support for ADHD are needed. In phase 2 workshops will develop the intervention based on the information gathered in phase 1. In phase 3 a different group of children and families will test the intervention and provide outcomes before and after (including ADHD and mental health symptom measures). Phase 4 will use feedback from the user testing in phase 3 to further improve the intervention.

Recruitment will be done in two stages. Participants will first be recruited to the co-design element of the study and will participate in the co-design of the intervention. The researchers will recruit 10 children, their parent/guardian, and 10 professionals to participate in the co-

design. The second stage of recruitment will recruit 10 children and their parents/guardians that did not participate in the co-design of the intervention to test the intervention and complete outcome measures. Children recruited in both phases must be 5-11 years old and have a diagnosis of ADHD. They must also have a sufficient understanding of English to participate along with their parents/guardians and professionals. The intervention will be tested during the user testing phase for 6 weeks. Follow-up will be 8 weeks after the start of the intervention testing.

Intervention Type
Behavioural

Primary outcome(s)
ADHD symptomatology measured using the Conners' Global Index (parent version) (CGI-P) completed by the parent/guardian at baseline and 8 weeks

Key secondary outcome(s))
Current secondary outcome measures as of 16/12/2022:

1. Revised Children's Anxiety and Depression Scale (RCADS) (parent) – 47-item parent-report questionnaire measuring anxiety and depression (Chorpita et al 2011). Higher scores indicate increased likelihood of reaching the clinical threshold for anxiety and/or depression.
2. Nature Connectedness Index (NCI) – 6-item child-report questionnaire collecting the degree to which children aged 7-15 feel connected to nature. (Richardson et al., 2019). Higher scores indicate more feelings of connection to nature.
3. A bespoke demographics questionnaire. Completed at baseline only.
4. A bespoke parent-report questionnaire measuring acceptability and accessibility. This will include a measure of adherence to the intervention, sessions completed, and a free response box for any additional feedback. Completed at 6 weeks only.
5. A bespoke child-report questionnaire measuring acceptability.
6. A self-report diary for parents and young people allowing for day-to-day reflections on using the intervention. Completed as often as possible for participants.

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Previous secondary outcome measures:

1. Anxiety and depression measured using the Revised Children's Anxiety and Depression Scale (parent version) (RCADS-P) completed by the parent/guardian at baseline and 8 weeks
2. The child's experiences and the acceptability of the intervention measured using a self-report diary completed daily throughout the 6-week intervention
3. Acceptability, accessibility, and fidelity of the intervention measured using a bespoke questionnaire completed by the parent/guardian at 8 weeks
4. Demographic information about the participants collected using a bespoke demographics questionnaire at baseline only

Completion date
31/08/2023

Eligibility

Key inclusion criteria

Current inclusion criteria as of 16/12/2022:

1. Child participants must be between 5-11 years of age and have a diagnosis of ADHD.
2. Children and their parents/guardians must have a sufficient understanding of English to participate and must live in Yorkshire, UK.

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Previous inclusion criteria:

1. Child participants must be between 5-11 years of age and have a diagnosis of ADHD
2. Children, their families, and professionals must have a sufficient understanding of English to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
11 years

Sex
All

Total final enrolment
51

Key exclusion criteria
Children who pose a risk of harm to themselves or others and children who would not be able to participate in the focus groups or user testing due to additional difficulties

Date of first enrolment
30/05/2022

Date of final enrolment
24/02/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds and York Partnership NHS Foundation Trust
2150 Century Way
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Study participating centre
The University of York
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Study participating centre
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Sponsor information

Organisation
Leeds and York Partnership NHS Foundation Trust

ROR

https://ror.org/00n635c12

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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. Requests should be made to Hannah Armitt (hannah.armitt@nhs.net) and will be considered by the study management group which includes the co-leads of the study and co-applicants on a case by case basis. The data that will be available is that collected during the user testing phase including data from two timepoints (baseline and 8 weeks) for the CGI-P, the RCADS-P, the self-report diary, and the bespoke acceptability questionnaire. It will be completely anonymised prior to sharing so that no participants are identifiable. The data will only be shared if requested through the named contact and if the study management group approve the request. Criteria for sharing include non-commercial research within the field of child mental health for any type of analysis. Consent for data to be made available to other researchers will have been obtained from participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/12/2024	09/01/2025	Yes	No
Protocol article		20/09/2022	27/09/2022	Yes	No
Other publications		22/06/2024	17/07/2024	Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.4	14/07/2022	02/08/2022	No	No
Protocol file	Full protocol version 1.3	14/12/2022	15/12/2022	No	No
Protocol file	User testing version 1.4	01/12/2022	15/12/2022	No	No
Protocol file	version 1.5	08/02/2023	08/02/2023	No	No
Protocol file	version 1.5	08/02/2023	08/02/2023	No	No
Protocol file	version 1.4	08/02/2023	08/02/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes