Protocol

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

(CONIFAS)

Full protocol

Chief investigators: Dr Hannah Armitt and Dr Peter Coventry

Principal Investigator: Professor Piran White

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Trial Contacts

Trial Contacts

Name	Affiliation	Study role	Contact details
Dr Hannah Armitt	Humber Teaching NHS Foundation Trust	Chief Investigator	hannah.armitt@nhs.net
Dr Peter Coventry	University of York	Chief Investigator	peter.coventry@york.ac.uk 01904321528
Professor Piran White	University of York	Co-investigator	piran.white@york.ac.uk
Ellen Kingsley	Leeds and York Partnership NHS Foundation Trust	Trial manager	e.kingsley@nhs.net 07870992859
Leah Attwell	Leeds and York Partnership NHS Foundation Trust	Research assistant	leah.attwell@nhs.net 07790892045
Sinead Audsley	Leeds and York Partnership NHS Foundation Trust	Sponsor Contact	sinead.audsley@nhs.net 07779 416847

Co-applicants

Name	Affiliation	Study role	Contact details
Megan Garside	Leeds and York Partnership NHS Foundation Trust	LYPFT oversight	megan.garside@nhs.net
Andrew Steele	Yorkshire Wildlife Trust	Co-investigator	andrew.steele@ywt.org.uk
Kat Woolley	Yorkshire Wildlife Trust	Co-investigator	kat.woolley@ywt.org.uk
Michael Hussey	ADHD Foundation Limited	Co-investigator	mike.hussey@adhdfoundation.org.uk
Natasha Green	PPI representative	PPI Lead	natasha.green5@nhs.net

Trial Summary

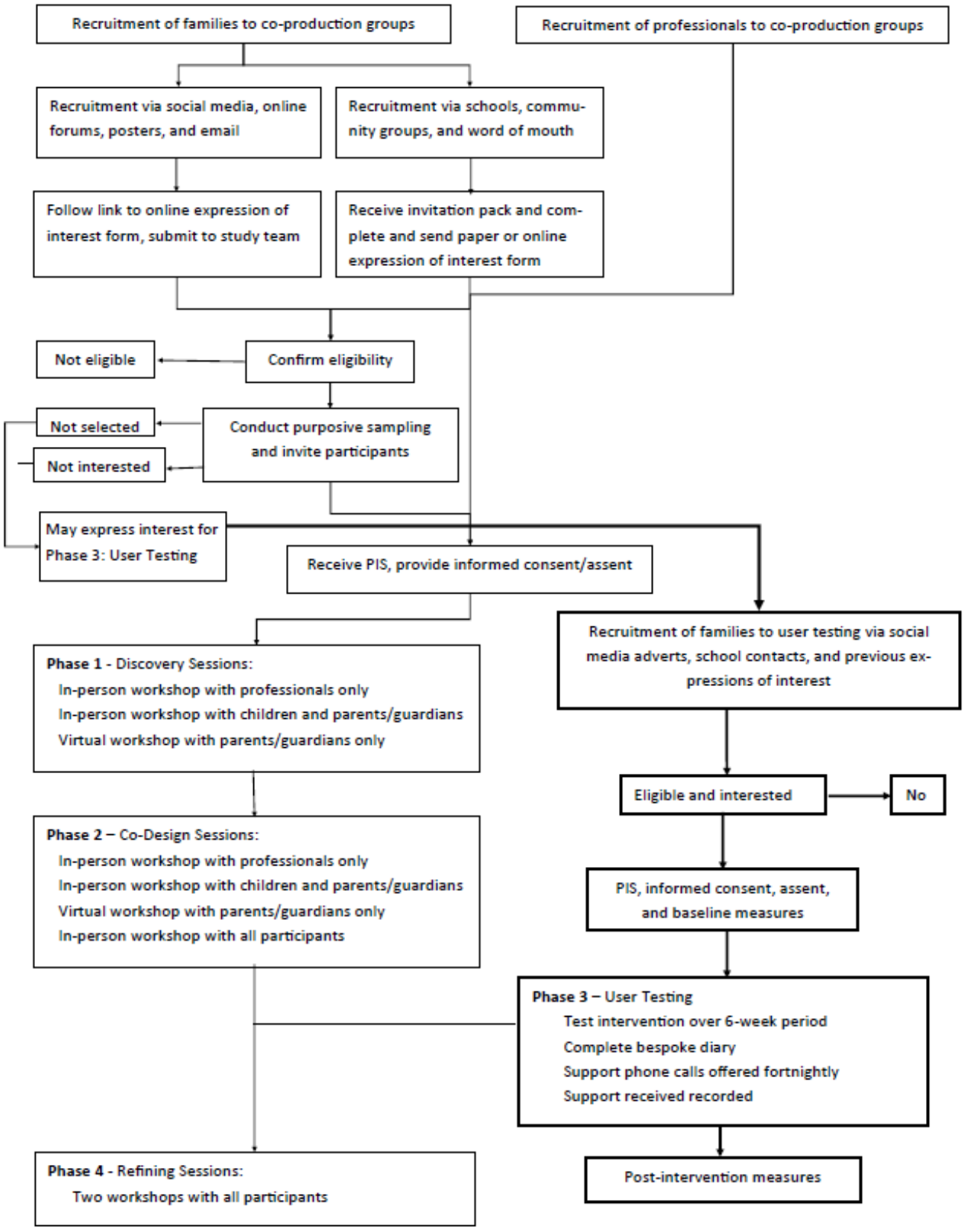
Trial Title	CO-production of a Nature-based Intervention For children with ADHD Study
Internal ref. no. (or short title)	CONIFAS
Trial Design	Co-production and user testing of a new intervention
Trial Participants	Children and young people with ADHD, their parent/guardian, and professionals
Planned Sample Size	50 (10 child-parent/guardian dyads and 10 professionals for phases 1, 2, & 4; 10 separate child-parent/guardian dyads for phase 3)
Intervention duration	6 weeks (user testing phase)
Follow-up duration	6 weeks after start of intervention testing (user-testing phase)
Planned Trial Period	18 months
Objectives	1. Recruit a co-production team of children and families with lived experience of ADHD, voluntary organisations working in green spaces, NHS professionals, clinicians and researchers. Define the problem and discuss ways to address it (Phase 1) 2. Use aspects of existing campaigns (such as the five 'Ways to Wellbeing' and Wildlife Trust's 30 Days Wild) to produce a new intervention that is appropriate and acceptable for this population through co-production workshops (Phase 2) 3. Conduct user testing to refine the co-produced intervention, measuring outcomes in terms of symptom manageability and acceptability, accessibility, and usability (Phase 3) 4. Refine the intervention from the previous phases (Phase 4)
Outcome measures (user-testing phase)	1. Conners' Global Index parent version (CGI-P) 2. Revised Children's Anxiety and Depression Scale (RCADS) (parent) 3. A bespoke demographics questionnaire 4. A bespoke parent-report questionnaire measuring acceptability and accessibility. 5. A bespoke child-report questionnaire measuring acceptability. 6. The Nature Connectedness Index (child-rated) 7. A self-report diary for parents and young people allowing for day-to-day reflections on using the intervention
Method of delivery	Workshops in phases 1, 2, and 4. Self-delivery at home and user-preferred outdoor locations during phase 3.

Key words: ADHD; intervention; nature; outdoors; child; adolescent; co-production, user-testing

Abbreviation List

ADHD:	Attention Deficit Hyperactivity Disorder
AE:	Adverse Event
CAMHS:	Child and Adolescent Mental Health Services
CI:	Chief Investigator
CONIFAS:	CO-production of a Nature-based Intervention For children with ADHD Study
DSM-IV:	Diagnostic and Statistical Manual of Mental Disorders
EOI:	Expression of Interest
GP:	General Practitioner
ICD-10:	International Classification of Diseases
LYPFT:	Leeds and York Partnership NHS Foundation Trust
NHS:	National Health Service
NICE:	National Institute for Health and Care Excellence
NIHR:	National Institute for Health Research
OMG:	Operational Management Group
PIS:	Participant Information Sheet
PPI:	Patient and Public Involvement
RA:	Research Assistant
REC:	Research Ethics Committee
RfPB:	Research for Patient Benefit
SAE:	Serious Adverse Events
SENCO:	Special Educational Needs Co-ordinator
SMG:	Study Management Group
TC:	Trial Coordinator
UK:	United Kingdom
YWT:	Yorkshire Wildlife Trust

Study Flow Chart



Study Protocol

Development of a Nature based Intervention for Children with ADHD

1. Background

1.1 ADHD

Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental condition characterised by inattention, hyperactivity and impulsivity. It is estimated to affect 2% of the adult population in the UK and between 3-5% of children in the UK (NICE 2018). For children with ADHD, these symptoms can have a significant impact on their daily functioning in the form of difficulty concentrating and being over-active regardless of setting. Children with ADHD often have comorbid mental health conditions (e.g. autism, speech and language difficulties, anxiety, low mood), poorer social and emotional wellbeing, and face challenges in academic, relational, and behavioural domains (Vibert, 2018).There is an association between low socio-economic status and an increased likelihood of ADHD diagnosis (Russel et al, 2016), indicating inequalities in this population.

1.2 Current treatment for ADHD

Children with a diagnosis of ADHD often have poorer outcomes than their typically developing (TD) peers and increased likelihood of educational difficulties, relationship breakdowns, and the development of co-morbid mental health difficulties (Vibert, 2018). Early identification and support can prevent the development of further mental health conditions in ADHD and increase quality of life. Current health care provision, however, particularly mental health care, has been shown to not meet needs (Children's Commissioner, 2018). It is also often focused on medication, which carries risks and does not always have good treatment adherence (Mattingley et al, 2017).

Studies report that at least 50% of referrals to child mental health clinics are for assessment and treatment of ADHD (Salomone et al., 2015), but there are long waiting lists for treatment access through child and adolescent mental health services (CAMHS). It was found that 6% of families wait over 12 weeks for a first appointment with CAMHS and 48% of families have their referrals closed before treatment is offered (NHS Digital, 2019). The estimated UK annual healthcare (NHS, social care and education) resource costs associated with treating ADHD in adolescents has been reported as £670 million, equating to a mean cost per adolescent of £5493 (Telford et al, 2013). It is also reported that at time of diagnosis, families do not routinely receive appropriate intervention (Children's Commissioning Report, 2018), which can lead to deterioration in the child's wellbeing.

Children and young people are negatively impacted by wait times and limited access to intervention, but there is also a negative impact on their parents or guardians and caregivers. The Caregiver Perspective on Paediatric ADHD study reported 38% of caregivers (n=2872) had been late for work in the past month due to their child's ADHD, and that 31% of caregivers

(n=3688) had altered their employment status (Flood et al, 2016). Telford et al (2013) identify the need to develop and evaluate early interventions which have the potential to reduce the longer-term burden of ADHD.

1.3 Nature-based interventions

There is consistent evidence that engagement with nature is beneficial for all children and young people in terms of physical activity levels, health outcomes, increases in wellbeing, reduced stress, and developing a positive affinity with nature (Sheldrake et al, 2019). There is evidence to suggest that engaging in outdoor activity, even when the weather is colder, can be beneficial to development and mental and physical health (Mutz & Müller, 2016). The potential of preventative nature-based interventions is becoming increasingly recognised, with recommendations for increases in the public health budget for programs promoting access to green space (Public Health England, 2020). Current government policy aims to increase access to green spaces to improve mental and physical health (Public Health England, 2020).

For children with ADHD, increased exposure to green spaces was strongly associated with reduced ADHD diagnosis (Donovan et al, 2019), reduced need for medication, and symptom reduction (Tillman et al, 2018). Green/blue spaces help alleviate ADHD symptoms via the availability of space and the associated benefits of physical activity to 'burn off' excess energy (Ulrich et al, 1991). Natural spaces also provide a multi-sensory space, removing external distractions of modern life such as technology, which counteracts ADHD symptoms that make it difficult to stay focussed (Taylor et al, 2001). Additionally, the relaxing effects of natural spaces can impact on a number of behavioural difficulties seen in ADHD (Van den Berg, 2011).

The New Economics Foundation (2008) has developed the five 'Ways to Wellbeing' (Connect, Be Active, Take Notice, Learn and Give), an evidence-based framework using structured natural activities to overcome inequalities of access and improve mental health. Although this is promising and aligns with recent recommendations (Public Health England, 2020), as yet there are no well evidenced and tested green interventions for use in the target population or for use in the NHS in Child and Adolescent Mental Health services (CAMHS).

1.4 Study Summary

This study will use a co-production methodology to create a nature-based intervention for children and young people with ADHD and their families to help manage the impact of ADHD symptoms on their lives. Four phases will be used based on the Design Council's Double Diamond model (Design Council, 2017) which includes four phases: Discover, Define, Develop, and Deliver. These phases will map on to four phases of the research study: Phase 1 involves discovery workshops to understand the problem (objective 1), phase 2 involves intensive co-production workshops to define and develop the intervention (objective 2), phase 3 involves user testing to deliver the intervention (objective 3) and phase 4 includes refining the intervention based on phase 3 outcomes (objective 4). This protocol covers all phases of the research; however, the study will be submitted for ethical review in two parts with two separate protocols. Part one will cover the co-production element of the study and part two will cover the user-testing of the co-produced intervention.

2. Rationale

Current NICE (2018) guidelines for children with ADHD recognise the need for a healthy lifestyle through physical activity and social connectedness. Nature-based interventions would align with this through their multiple benefits including opportunities for physical activity, increases in wellbeing and health outcomes, reduced stress, and connectedness with nature (Sheldrake et al, 2019). Although evidence shows that nature-based interventions can be highly effective at supporting children with ADHD, there is no bespoke intervention that has been developed and rigorously tested in this population.

This study intends to create a novel, co-produced intervention for use with children with ADHD to reduce the impact of symptoms and make them more manageable in day to day life. The intervention can be situated in the NHS with Child and Adolescent Mental Health services (CAMHS) well placed to support the development of the intervention for use with this patient population. We will work closely with them throughout the study and have included clinical staff in initial discussions during proposal development. This will ensure links between the end users (families of children with ADHD) and local mental health services are created. Additionally, links between a local nature partner (Yorkshire Wildlife Trust), The University of York, and the ADHD Foundation will be made which will add value to current practice and knowledge.

Co-production has been chosen as the methodology as its central value is the development of more equal partnerships between people who use services, carers and professionals. It is hoped co-production will support development of an intervention that is meaningful for the population using the service. Co-production has been linked with better outcomes for people who use services and can support the development of stronger relationships by forging strong links with service providers.

3. Objectives

1. Create a co-production team of children and families with lived experience of ADHD, voluntary organisations working in green spaces, NHS professionals, clinicians and researchers. Investigate the strengths and difficulties associated with an ADHD diagnosis in children and how nature can be used to support them (Phase 1).
2. Produce a new intervention that is appropriate and acceptable for this population through discovery and co-production workshops, using existing campaigns (such as the five ‘Ways to Wellbeing’ and Wildlife Trust’s 30 Days Wild) for inspiration (Phase 2).
3. Conduct user testing of the prototype intervention to assess accessibility, feasibility, and usability, and to capture data about impact on participant health outcomes (Phase 3).
4. Refine the intervention from the previous phases (Phase 4).

4. Outcome measures

Outcome measures for this study will only be used in phase three, the user testing phase, to gain information about the effectiveness and acceptability of the co-created intervention. The measures will be collected at baseline, immediately before the 6-week intervention begins, and 6 weeks after baseline unless otherwise stated below.

The following outcome measures will be used:

1. Conners' Global Index parent version (CGI-P) – 10-item parent-report questionnaire used to characterise patterns of behaviour related to ADHD symptomatology (Connors et al 2011). Higher scores indicate more severe ADHD symptomatology.
2. 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.
3. 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.
4. A bespoke demographics questionnaire. *Completed at baseline only.*
5. 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.*
6. A bespoke child-report questionnaire measuring acceptability.
7. 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.

The CGI-P and RCADS are routinely used in CAMHS services and have been selected for this purpose.
Results will be reported descriptively (e.g. mean scores, percentages, pre- and post-change scores). The outcomes from this group will be sufficient to refine the intervention in preparation for testing in a feasibility trial.

5. Study Design and Setting

The present study will use co-production methodology, using the four phases of the Design Council's Double Diamond model (Design Council, 2017) which map onto the study objectives as listed above. In the first phase, the team will 'discover' what the challenges are for those with ADHD and how nature-based interventions may support them by creating a co-production team of children and families with lived experience of ADHD and professionals from voluntary organisations and the NHS. In phase two, the 'define' phase, the team will seek to create an intervention using elements from existing campaigns (e.g. Ways to Wellbeing) which meets the needs identified by the co-production team in the discovery phase. The third phase ('develop') will test the intervention with children and families with lived experience of ADHD to allow for further development arising from the feedback collected via outcome measures which focuses on symptom manageability. This phase will also assess the acceptability and useability of the created intervention. In phase four ('deliver'), the final product is created ready for a wider launch (feasibility). Practical co-production resources from The Institute for

Research and Innovation in Social Services (Vallely, 2018), will be used at each phase involving co-production (1, 2, and 4). These resources include the 'thinking hats' tool which enables group members to consider the challenge from different perspectives and a pathway tool which will support the team to keep track of the intervention's development.

This protocol covers all phases of the research; however, the study will be submitted for ethical review in two parts with two separate protocols. Part one will cover the co-production element of the study (phases 1, 2, and 4) and part two will cover the user-testing of the co-produced intervention (phase 3).

6. Participants and Eligibility Criteria

6.1 Inclusion criteria

Participating children and young people must:

- Be aged between 5-11 years
- Have a diagnosis of ADHD as reported by their parents/guardians.
- Have sufficient understanding of English to participate in the co-production events and/or the intervention testing.

Participating parents/guardians and professionals must:

- Have sufficient understanding of English to participate in the co-production events and/or the intervention testing.

Participants for the co-production element (phases 1, 2, and 4) are children and young people aged between 5-11 years with lived experience of ADHD, their parent/guardian, and professionals from voluntary agencies or the NHS. All participants will live or work in the local area and be able to travel to the designated meeting location; Barlow Common, Selby, North Yorkshire. These areas will include York, East Riding of Yorkshire, West Yorkshire, North Yorkshire, and South Yorkshire.

Participants for the user-testing element (phase 3) are children and young people aged between 5-11 years with lived experience of ADHD and their parent/guardian. Participants will be located in Yorkshire, UK and will not be required to travel to specific locations for this phase other than outdoor locations they prefer.

6.2 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 significant additional difficulties will not be eligible to take part. Children with comorbid diagnoses (e.g. autism, physical difficulties) will be supported to participate with recognition that additional considerations in accessing outside spaces may arise. Any relevant risks will be assessed during the consent procedure.

7. Trial Procedures

7.1 Expression of Interest Procedure – *co-production recruitment only*

As this study involves the creation of a new intervention by community members, we want the intervention to meet the needs of a range of families. We thus aim for our families participating in the co-production phases (1, 2, & 4) especially, to represent a diverse range of life experiences. To meet this aim, we will conduct an Expression of Interest (EOI) procedure for recruitment to the co-production phases in which interested families will complete a short demographic questionnaire including questions on their family structure and locality. We hope that this will capture the needs of children across our age range, different cultures, large and small families, parent/guardian education levels, and families in urban, rural, and coastal locations. This procedure will not be used for the user-testing phase of the study.

Parents/guardians will be invited to complete the EOI survey to register their interest through an online survey which can be circulated via email and through QR codes on study posters. Families who contact the research team but cannot access the online form will be given the option of completing the survey over the phone or via post. The EOI survey will close on an agreed upon date. All parents/guardians completing the form will be made aware that expressing interest does not guarantee that they will be invited to take part due to the use of purposive sampling. This will be thoroughly explained to parents/guardians prior to their completion of the survey. They will also have the option to provide consent for the research team to store their details for contact about the user testing phase of the study (phase 3), though this will be entirely optional. If they agree, these details will be stored on a password protected spreadsheet on secure drives on NHS computers. This process will be repeated for phase 3 recruitment. See section 11 for further details of data handling.

7.2 Recruitment

Recruitment to the study will be conducted during two of the four study phases – phase 1 and phase 3. Phase 1 will recruit 10 child-parent/guardian dyads and 10 professionals to co-produce the intervention. Phase 3 will recruit a further 10 child-parent/guardian dyads to conduct user testing of the co-produced intervention. Families for both recruitment phases will be identified through social media - including relevant parenting forums - through posters, via local council advertisements, through schools, and via community groups. Professionals will be recruited through advertisements distributed through existing professional links and social media. All circulation methods will include the study team's contact details. All interested families and professionals will be given a copy of the parent/guardian participant information sheet (PIS), the child PIS (which contains study information tailored to children aged 5-11), or the professionals PIS.

This protocol covers all recruitment for the research; however, the study will be submitted for ethical review in two parts with two separate protocols, each of which will cover one of the recruitment phases. Part one will cover the co-production recruitment process (phase 1) and part two will cover the user-testing recruitment process (phase 3).

7.2.1 Co-production Recruitment

Children and their parents/guardians will be recruited via purposive sampling from the EOIs received. 10 parent-child dyads will be selected based on representative characteristics.

This selection will be based, in part, on demographic statistics for the region i.e. socio-economic information gained from participant post codes. Our selection process and criteria will be transparent from the beginning, and all OMG members will be present during this selection. Participant selection will be reported to the SMG for approval.

If selected, the families will be encouraged to re-read the PIS and to discuss the child PIS with their child. They will have a discussion with the research team about the study and be able to ask any questions. If they would like to proceed, parents/guardians will complete a consent form which provides consent for their and their child's participation in the study. The children can complete an assent form if deemed appropriate, though this is not necessary as parental consent on their behalf is sufficient. However, if any parents/guardians wish to participate but their child does not, they will not be enrolled in the study. If any of the selected 10 families no longer wish to take part at the consent stage, the study team will use the other received EOIs and select new potential participants, again based on representativeness.

The 10 professionals will not be required to complete an EOI procedure. We aim to recruit a mixture of medical, educational, and outdoor-activity professionals. This may include, but is not limited to, NHS CAMHS workers, school special educational needs coordinators (SENCOs), charity staff, and outdoor-activity staff. Professionals will be recruited from northern and regional CAMHS, third sector, and education settings via email and telephone contact. A participant information sheet will be provided, and the study will be explained in detail with opportunity for any questions. Informed consent to participate will be then obtained.

7.2.2 User-Testing Recruitment

The study will be advertised through social media - including relevant parenting forums - through posters, via local council advertisements, through schools, and via community groups. Parents/guardians will be invited to contact the research team to hear more about the study and will be given a full explanation. Those interested in participating will be provided with the approved study parent/guardian participant information sheet (PIS) and child PIS (including study information tailored to 5–11-year-olds) and will be given the opportunity to ask any questions they may have.

Some families have already consented to us holding their contact details and contacting them regarding user testing of the intervention via submitting their interest to the first phase of this study. These families will be contacted directly.

7.3 Screening and Eligibility Checks

Eligibility checks for both phases of the research will be conducted once parents/guardians and children have expressed an interest in participating and have been given a PIS and detailed description of the study by a researcher. Eligibility checks will take place prior to informed consent/assent being obtained.

7.4 Incentives

Families participating in the co-production phases will receive £20 worth of Love2Shop shopping vouchers following each in-person co-production workshop as an incentive and expression of gratitude for their time given to the study. There are five in-person workshops for families so they could receive up to £100 in shopping vouchers.

User-testing families will receive a £20 Love2Shop voucher following completion of their follow-up outcome measures. Families with more than one participating child will receive a £20 voucher for each child they complete the final outcome measures for.

7.5 Informed Consent

Participation in the study will be entirely voluntary and written informed consent (and assent where appropriate) from participants will be obtained prior to any involvement in the discovery or co-production groups (phase 1 recruitment) or data collection (phase 3 recruitment). Participation in the study will be entirely voluntary for all participant types (children, parents/guardians, and professionals) and written informed consent will be obtained before workshop attendance. Participants under the age of 16 will be invited to complete an assent form, but this will not be required (the research team will defer to parents/guardians for the appropriateness of this). Parent/guardian consent will cover their own participation and that of their child. Where a child declines to participate they will not be included.

7.6 Data Storage

Data provided by participating families will be stored securely on encrypted NHS computers and in locked filing cabinets in locked office on NHS premises. Identifiable details of consenting participants including name, address, and contact details will be entered onto a password-protected spreadsheet and stored on a secure NHS drive accessible only through secure logins on NHS computers. identifiable information gathered will be stored separately from outcome measure data anonymised via ID codes.

Participant personal details will be retained for 6 months after the end of the study and then destroyed unless they have consented to being contacted about future research. This 6-month period will allow for dissemination of findings. Research data will be retained for 5 years as per the Sponsor's (Leeds and York Partnership Foundation NHS Trust) regulations.

7.7 Withdrawal Criteria

Any participant can withdraw from the study at any time without having to provide a reason for withdrawal. During the co-production phase, if a parent or guardian wishes to withdraw from the study, it will be clarified whether they would like to withdraw themselves and their child or young person or just themselves. If a child wishes to withdraw, it will be clarified whether their parent wishes to continue participating.

During the user testing phase, if one member of a dyad wishes to withdraw, then both parent and child will be withdrawn. Any data collected prior to withdrawal will be retained unless the

participant expresses that they wish for it to be destroyed. This will be confirmed with them at the stage of withdrawal. We will ask participants for their reason for withdrawal to record and monitor any issues, but we will remind participants that they do not have to provide a reason.

8 Study Activities

The CONIFAS study design is informed by and mapped onto the Design Council's Double-Diamond model of co-production (Design Council, 2017). As such it is split into four phases. This protocol covers all phases of the research; however, the study will be submitted for ethical review in two parts with two separate protocols. Part one will cover the co-production element of the study (phases 1, 2, and 4) and part two will cover the user-testing of the co-produced intervention (phase 3).

8.1 Phase One - Discover

The discovery phase aims to understand and define the problem at hand, the potential methods of change, any barriers to change, and which nature-based activities may be helpful for children with ADHD. This will occur over three separate workshops:

1) An in-person, half-day event with relevant professionals who work with children with ADHD.
2) An in-person, half-day event with children and their parent/guardian to gather children's views and participate in some preliminary nature-based activities.
3) An online workshop with just parents/guardians to gather parent/guardian views.

The workshops will be led by the research team and activities will be facilitated by the Yorkshire Wildlife Trust staff.

8.2 Phase Two - Define

This phase will focus on the development of the intervention ready for user testing. This will occur across four workshops:

1) An in-person, half-day event with professionals.
2) An in-person, half-day event with children and parents/guardians.
3) An online workshop with parents/guardians.
4) An in-person, half-day event with all participants.

The workshops will be led by the research team and activities will be facilitated by the Yorkshire Wildlife Trust staff.

8.3 Phase 3 - Develop

This phase will involve recruiting 10 new child and parent/guardian dyads to conduct user testing of the designed intervention. This phase will be submitted for ethical approval separately from the other phases once the first two study phases are complete and more is known about the co-produced nature-based intervention.

During phase 3, recruited participants will complete the following outcome measures:

1. Conners' Global Index parent version (CGI-P) – 10-item parent-report questionnaire used to characterise patterns of behaviour related to ADHD symptomatology (Connors et al 2011). Higher scores indicate more severe ADHD symptomatology.
2. 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.
3. 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.
4. A bespoke demographics questionnaire. *Completed at baseline only.*
5. 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.*
6. A bespoke child-report questionnaire measuring acceptability.
7. 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.

Data collection will be carried out by the study's research assistant or trial coordinator via virtual meeting platforms (e.g. Zoom, Teams) or via post. We anticipate that completion of both the baseline and 8-week follow-up questionnaires will take between 30 and 60 minutes. The diary is a daily child-completed measure and may take between 5 and 15 minutes to complete.

8.4 Phase 4 - Deliver

In the final phase, all 30 participants from phases 1 and 2 will attend two workshops to look at the results of the user testing phase, to make any changes to the intervention, and to finalise the intervention and any intervention materials for wider use.

9. Study Intervention

9.1 Co-production

During phases one and two of the CONIFAS research study, a nature-based intervention for children with ADHD was co-produced by families with lived experience of ADHD, relevant professionals, and the study team. Participants and the study team met multiple times to first discover what we needed to know about to create this intervention and to then discuss what it should look like, contain, and achieve.

Summaries of co-production workshops were produced and stored on a secure limited-access University of York shared Google drive. The process and outputs of the co-production phase will be written up for a separate publication. The following key points were raised in the workshop discussions and have informed the final co-produced intervention:

- The intervention needs to focus on effectively engaging children with the natural world, but also on building the confidence and skills of parents/guardians in nature.
- Education about the benefits of nature needs to be included for parents/guardians and children.
- Needs to be accessible for any family and contain information on what nature is, how to access it regardless of where you live, and how to prepare for it/what to bring.
- Children going into nature will likely already know what they want to do so activities should be less prescriptive and offered more as a guide or prompt where children need ideas. This process needs to be genuinely child-led.
- Delivery of the intervention will need to be supported, for example, via scheduled phone calls from a mental health professional.
- Parents/guardians and children should be directed to additional education and activity ideas resources, for example, those provided through partner agencies and organisations such as the ADHD Foundation and Wildlife Trusts.

9.2 Contents

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.

9.3 Theoretical basis of intervention materials

The education booklets include information on the proven effects of nature on children's well-being and ADHD symptomatology as well as support to find and use local nature spaces (including how to find and use urban nature spaces). There is a daily challenge aspect included which encourages families to interact with nature for 10 minutes every day with further information and ideas on how to extend nature usage. 'Sensory circuit' activities are also introduced, as well as how to build confidence and outdoor risk-management.

The education booklets are based on published evidence about good practice in using nature-based interventions and working with neurodiverse children. All facts and figures referenced in the booklets are from peer-reviewed research. The types of activities suggested and detailed in the booklets and activity cards are underpinned by nature connectedness principles

(National Trust, 2021) which have been shown to affect aspects of well-being (Sheffield et al., 2022). The 10-minute challenge is based on observational evidence which suggests that a 'dose' of nature ranging upwards of 10 minutes per day can lead to positive impact on health and wellbeing (Hunter, Gillespie, & Chen, 2019; White *et al.,* 2019). Intervention-users are encouraged to engage in nature for more than 10 minutes as there is evidence that time spent in nature and improvements in well-being are positively correlated up to 90 minutes (White et al., 2018). 'Sensory circuits' are a series of 5-minute activities beginning with an 'active' task to wake up the body, followed by an 'organising' task which encourages the brain and body to feel connected, and finishing with a 'calming' exercise which soothes the individual and primes them ready to focus. Sensory circuits are regularly used and recommended by the ADHD Foundation.

The activities in the children's education booklet are designed to educate and enthuse the child to take ownership of their nature-based activities and to feel involved in the process. It was recognised during the co-design workshops that children often already know how to play outdoors, can be resistant to having their play dictated, and benefit from taking a leading role in their play. For these reasons both child and parent/guardian are encouraged to follow the child's interests with appropriate direction and support.

The activity cards have been produced to especially help families who may be less familiar with how to play and explore outdoors or using nature. The cards provide quick and easy tasks which can be done with minimal resources and can be accessed quickly should the child feel they need or would benefit from more direction. The cards are organised into categories loosely based on the nature connectedness principles (active, body and senses, creative, learning, calming), and levels (easy, medium, hard). Breaking these activities into categories and levels will help the families to find a task which suits the child's abilities and feelings at that time. All activities are designed to incorporate exercise, sensory-based tasks, and/or nature appreciation.

The daily challenge calendar was designed as an incentive for families to build 10 minutes of nature usage into their daily routines. It should act as a visual reminder and as a reward/incentive for the child to feel encouraged by placing star stickers on days where they have completed 10 minutes or more. However, we recognise that it is important for this task to be described as a goal rather than a mandatory requirement. The core goal for this intervention is for families to build their confidence in nature at a pace and manner which suits them.

10.Statistics and Data Analysis

10.1 Sample Size Calculation

During recruitment to the co-production phases of the study, a total of 30 participants will be recruited: one group of 10 children, one parent/guardian for each child, and one group of 10 professionals. Group size is based on guidance for co-production methodology that allows for varied views but equal participation (Vallely, 2018).

We will recruit a further 10 child-parent/guardian dyads (totalling 20 participants) for the user-testing phase (phase 3). A sample of 10 has been deemed sufficient for assessing preliminary acceptability and accessibility (Hertzog, 2008). We will allow for recruitment over this total and will allow more than one eligible child per family to participate.

10.2 General Approach to Data Analysis

Data analysis will only occur in phase 3, the user-testing phase. This will include:

- Descriptive analysis and reporting of demographic and medical information.
- Descriptive analysis and mean calculations of the bespoke acceptability and accessibility questionnaires.
- Nature Connection Index (NCI) – Mean pre- and post- changes in scores.
- Conners' Global Index parent version (CGI-P) – Mean pre- and post- changes in scores.
- Revised Children's Anxiety and Depression Scale (RCADS) (parent) – Mean pre-and post- changes in scores.
- Basic qualitative analysis of the self-report parent diaries and verbal feedback during 'check-in' phone calls including final phone call post-follow-up measures.

11.Data handling

11.1 Data collection tools and source document identification

Data collection will be completed by a trained RA with up-to-date Good Clinical Practice training and a Disclosure and Barring Service check. Data collection from parents/guardians and children will be carried out once participants have provided informed consent/assent. We estimate that parent/guardian completion of the outcome measures at baseline and 6 weeks will take between 30 and 60 minutes. The diary is a parent/guardian-completed measure which they will be encouraged to complete as often as possible. It may take between 2 and 10 minutes to complete each time. Child completion of outcome measures will take between 10 and 20 minutes.

Data collection will be offered via online meeting platforms (e.g. Zoom, MS Teams) or via phone call. Face-to-face data collection may be offered where necessary (e.g. participant preference, no access to any technology). Children will be encouraged to complete measures with the research team during these meetings but may complete them at other times with parental support if they struggle to engage.

All measures used here are self-reported by parents/guardians or children and will form the basis of all source data during the study.

11.2 Data handling and record keeping

Study data will be extracted from source documents and entered into password protected Microsoft Excel spreadsheets which will be stored securely on limited access secure drives

on NHS computers. Outcome measure data will not contain personal identifiable information but will contain the participant's unique ID.

Identifiable information (participant names and contact details) will also be collected and entered into password protected Excel spreadsheets stored securely on limited access secure drives on NHS computers, but access to these will be restricted to only research team members with appropriate privileges.

All data will be collected and stored in accordance with the Data Protection Act 2018, the General Data Protection Regulation, and LYPFT standard operating procedures (SOPs). Participant consent forms will include a statement affirming agreement with sharing anonymised data and an optional statement affirming agreement to being contacted about future research. From this there is potential for the data from this study to be made available to other researchers where participant consent has been given.

The sponsor will permit monitoring and audits by the relevant authorities. The co-leads will also allow monitoring and audits by these bodies and the sponsor, providing direct access to source data and documents, including secure spreadsheets. Any data monitoring and audits will be conducted in accordance with LYPFT SOPs.

11.3 Data Sharing

Anonymised participant data will be made available on request. Requests should be made to the main trial contact 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.

11.4 Archiving

Study documentation and data will be archived at a suitable time following database lock. All essential study documents will be retained as part of the study documentation. Following notification of study completion, all documentation and study data, except participant contact details (unless they have consented to being contacted for future research), will be stored securely for five years by LYPFT and will be accessible for inspections and audits.

12.Safety and Risk

12.1 Assessment and Management of Risk

We do not anticipate that participants will be subject to any substantial risks during this study. However, the focus of this study is on nature-based and outdoor activities, with workshop sessions involving participation in these activities and being outdoors (weather dependent). As such, usual risks associated with being outdoors may be expected including but not limited to slips, trips, sunburn, insect bites, stings, etc. All children will be attending with a parent/guardian or carer, and it will be deemed parent/guardian responsibility to monitor the children. All participants will be reminded of the risks, encouraged to proceed with caution, notified of any particular risk areas (slippery ground, etc.) and reminded to attend sessions wearing appropriate footwear and clothing with plenty of notice. Where

needed, additional clothing, particularly for cold or wet weather, will be provided by YWT on site. A risk assessment of the YWT site and the planned activities will be conducted.

Participants will be asked to complete a risk management form where they can report on relevant risks such as asthma, bee sting allergies, etc. Participants will be reminded before each session to bring any relevant medication including inhalers and emergency medication. It will be the responsibility of the participants (or their attending parents) to manage and administer their own medications.

Lunch will be provided for participants when they attend an in-person discovery or co-production session. All participants and attending staff members will be asked to report any allergies and intolerances to the study team, and these will be catered for accordingly.

The research team recognise that children with ADHD may struggle with listening to and retaining instructions due to the nature of their disorder. The researchers will ensure that instructions, particularly pertaining to any risks, are clearly communicated and that parents/guardians, carers, and staff are attentive to the children.

12.2 Adverse Events

Possible harm as a result of the study is expected to be minimal but will be monitored and recorded. An Adverse Event (AE) in this study may include outdoor activity-based risks or behavioural incidents including:

- Slips, trips, and falls
- Bug bites and stings
- Bumps and scrapes
- Significant emotional distress
- Verbal abuse
- Physical violence

All AEs will be assessed for seriousness and will be recorded as Serious Adverse Events (SAEs) if they:

- Result in death
- Are life-threatening
- Require hospitalisation or prolongation of existing hospitalisation
- Result in persistent or significant disability or incapacity

12.3 Collecting, Recording, and Reporting of Adverse Events

AEs that are considered related to the participation in this study, and all SAEs, will be reported to the CIs. SAEs considered to be related to the study and to be unexpected will be reported to the Sponsor and SMG as soon as possible. The OMG will regularly assess any arising AEs and the SMG will review all AEs during scheduled meetings and propose any actions accordingly.

During the user-testing phase, participants will be encouraged to report any arising AEs. The research team will be in regular contact with participants to check in on such events during two-weekly 'check-in' phone calls. Participants will also be encouraged to reach out to the research team at any time.

13. Study Management

The day-to-day running of the study will be managed by the Operational Management Group (OMG): Hannah Armitt, Peter Coventry (co-leads), Ellen Kingsley (TC), and Leah Attwell (RA). The OMG will meet on a monthly basis with communication in between meetings. The Study Management Group (SMG) involves the OMG and all co-applicants including the PI: Piran White (PI), Megan Garside (LYPFT), Kat Woolley (YWT), Mike Hussey (ADHD Foundation), and Natasha Green (PPI Lead). The SMG will meet every 3 months to provide additional oversight, guidance, and decision making.

14. Definition of End of Study

The study will end on the 31st of August 2023.

15. Ethical Review

The proposed study will be conducted in accordance with ICH Good Clinical Practice guidelines. This project does not require HRA approval in accordance with their guidance. The co-production phases of the study were submitted for ethical review by the University of York department of environment and geography research ethics committee (REC) and were approved on the 23rd May 2022. The user-testing phase was submitted to the same REC and approved on the 12th December, 2022.

15.1 Peer review

The proposed trial has been previously peer reviewed in line with the National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) funding process.

15.2 Patient and public involvement

The research team is committed to involving PPI in all parts of the study. A parent of a child with ADHD is a co-applicant on the study and will review all participant facing documents. Participant facing documents will also be reviewed by the sponsor's (LYPFT NHS) research patient ambassador. The nature-based intervention itself will be co-produced with families with lived experience of ADHD and with professionals who work with them. This intervention will then be tested by families with lived experience of ADHD.

15.3 Protocol, GCP, and regulatory compliance

Non-compliance with GCP and the study protocol will be monitored and recorded by the study team in accordance with LYPFT SOPs.

15.4 Financial and competing interests

There are no financial or competing interests to report. The Yorkshire Wildlife Trust property on which the in-person workshops will be held is free to enter, provides free parking, and has free amenities. Lunch will be paid for and provided by the research team and so no funds from participants attending the group sessions will be required.

Advice and guidance will be sought from Medipex in the creation of the intervention. The research team do not intend to capitalise upon the designed intervention and wish for it to be publicly owned.

15.5 Indemnity

To meet the potential legal liability for harm to participants arising from the design, conduct, and management of the research, NHS employees will be covered by NHS indemnity and University employees will be covered by their institution's insurance. Workshops will be held on Yorkshire Wildlife Trust premises, and relevant staff will be covered by their organisation's indemnity insurance. As the sessions will be led and designed by NHS staff, study participants will be covered by NHS indemnity insurance.

15.6 Amendments

All study amendments will be approved by the co-CIs and all substantial amendments will be approved by the CIs, the Sponsor, and the SMG prior to submission for ethical approval. Amendment history will be tracked by adopting version control and via an amendment log.

15.7 Post-study care

This study will not affect any treatment or support from schools, GPs, and/or community services received by participating children with ADHD, they will continue to receive this throughout. Should any additional needs be identified through the trial, advice for contacting support services will be provided by the research team. This may include advice about voluntary agencies, parent support groups, local authority support, health and disability teams within social care, and CAMHS.

16.Complaint Handling

The PIS will provide participants with contact details of the CIs, REC chair, and Sponsor in case of complaint.

17.Dissemination

The research team has a strong track record of successful dissemination of work funded by the NIHR and other funding bodies. We will begin to consider our dissemination strategy at an early stage of the project. PPI will be important in disseminating the results of this study in terms of where to share the results, the format of this, and the content. A dissemination strategy will be considered early in the project and will likely include the intention to publish the results of the research in an academic journal for which this study would be well suited.

Presentations of study findings will be taken to relevant research conferences, local research symposia and seminars for CAMHS, and child health and educational professionals. In addition, our PPI lead and further appropriate PPI and organisation members will be consultees in the development of dissemination strategy which will be effective in reaching families of children with ADHD. Additionally, we will produce a lay summary of the study results and the designed intervention that can be distributed to all study participants as well as relevant interest groups. We will publish findings on relevant websites such as the University and child mental health websites.

18.References

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19.Protocol Amendment History

Amendment No.	Protocol version no.	Date	Author(s) of changes	Details of changes made
1	1.1	01.06.2022	Ellen Kingsley	Study name change applied. All references to 'co-design' changed to 'co-production.' ISRCTN number and ethics approval for co-design phases added.
2	1.2	07.09.2022	Ellen Kingsley	YWT co-applicant replaced.
3	1.3	14.12.2022	Ellen Kingsley	Follow-up time-point specified as 6 weeks. Two additional outcome measures added (child-completed acceptability questionnaire and NCI), both approved by NIHR. Participants in UT phase specified. Allowing for over-recruitment added. Intervention details included. Ethics approval details added. References updated.