Protocol

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

(CONIFAS)

User Testing Phase Only (Phase 3)

Chief investigators: Dr Hannah Armitt and Dr Peter Coventry

Principal Investigator: Professor Piran White

Sponsor: Leeds and York Partnership NHS Foundation Trust

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Table of Contents

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Study Contacts

Study 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 coordinator	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

Study Summary

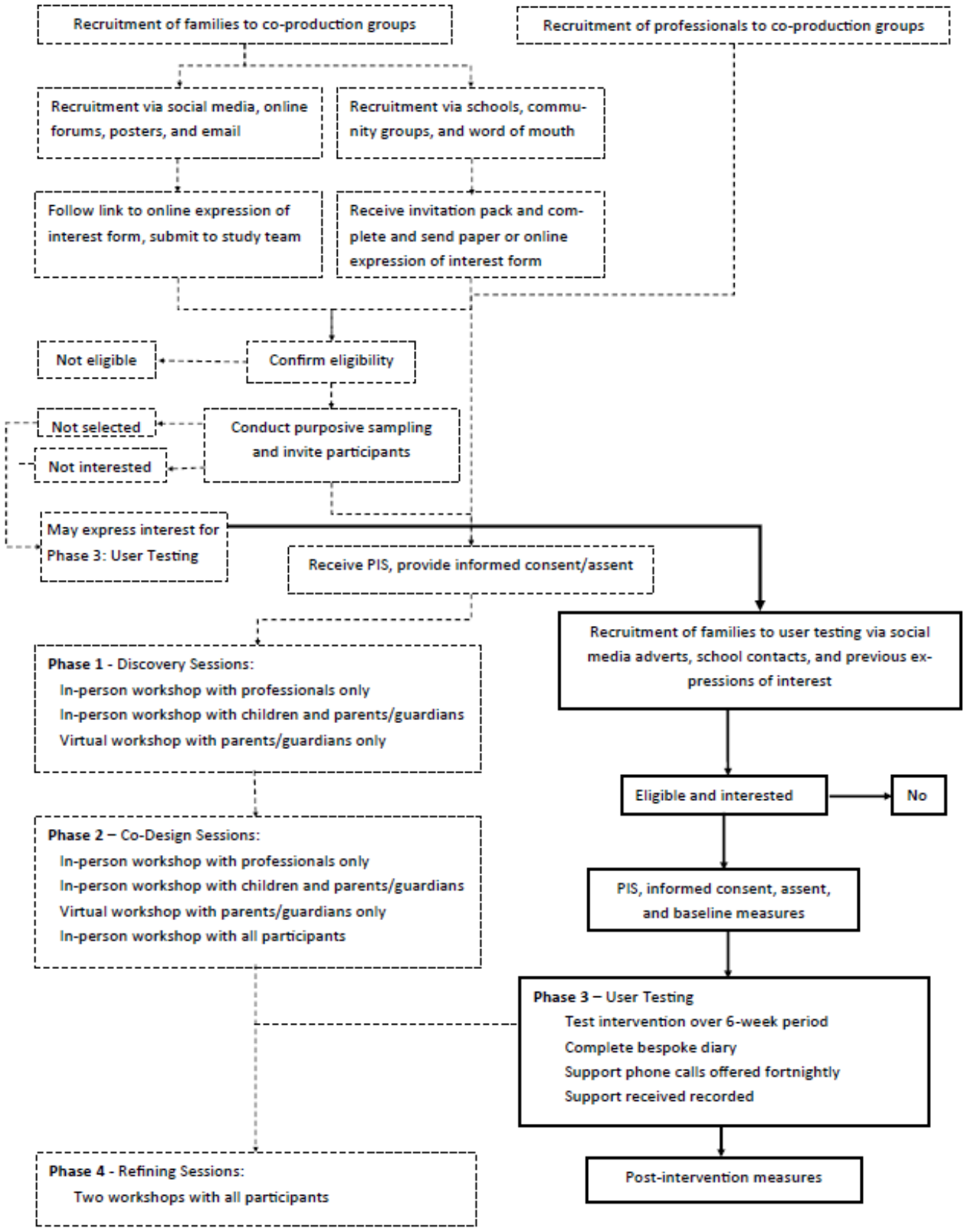
Study Title	CO-production of a Nature-based Intervention For children with ADHD Study
Internal ref. no. (or short title)	CONIFAS
Study Design	User testing of a co-designed intervention
Study Participants	Children and young people with ADHD and their parent/guardian
Planned Sample Size	20 (10 independent families with at least one child with diagnosed ADHD)
Intervention duration	6 weeks
Follow-up duration	6 weeks post baseline
Planned Study Period	4 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) – *separate co-production protocol* 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) – *separate co-production protocol* 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) – *separate co-production protocol*
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	Self-delivery at home and user-preferred outdoor locations

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 protocol describes the user testing phase of the CONIFAS research study. CONIFAS uses co-production methodology with the aim of creating 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 are planned based on the Design Council's Double Diamond model (Design Council, 2017): Discover, Define, Develop, and Deliver. These phases map on to the four study objectives. Phases 1 and 2 (covered by a separate *co-production protocol* [Armitt et al., 2022]) are now complete and involved discovery and co-production workshops to create a prototype nature-based intervention.

This protocol focuses on the methods and procedures for the user testing phase (phase 3) which aims to collect data about the acceptability and feasibility of delivering the intervention in more real-world settings and scenarios (objective 3). Phase 4, also covered in the *co-production protocol*, will include refining the intervention with the participant groups from phases 1 and 2 based on phase 3 outputs (objective 4).

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 tests a novel, co-produced intervention for use with children with ADHD to reduce the impact of symptoms and make them more manageable in daily life. The intervention has been designed with and by children with ADHD, their parents/guardians, and a group of relevant professionals. The intervention could go on to be situated in the NHS with Child and Adolescent Mental Health services (CAMHS) who are well placed to support the development of the intervention for use with this patient population. We have been working closely with them throughout the study and have included clinical staff in initial discussions during proposal development and intervention design. 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 have been made which will add value to current practice and knowledge.

The intervention has been co-produced as its central value as a methodology is the development of more equal partnerships between people who use services, carers and professionals. It is hoped that the developed intervention 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. We are now seeking to test the designed intervention with 10 independent families to measure whether it is accessible and acceptable, and to collect preliminary data on any effects on well-being and ADHD symptomatology.

3. Objective

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) – *separate co-production protocol*
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) – *separate co-production protocol*
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) – *separate co-production protocol*

4. Outcome measures

Outcome measures will be used to gain information about the efficacy and acceptability of the co-created intervention. The measures will be collected at baseline (immediately before the 6-week intervention begins) and at the 6-week follow-up timepoint 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 study.

5. Study Design and Setting

The prototype CONIFAS intervention will be tested with 10 independent families with lived experience of ADHD who have not previously been engaged with co-production. Participants will be asked to test the intervention in a self-led manner at home and/or at outdoor locations with support from the research team.

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.

All participants must have sufficient understanding of English to participate in the intervention testing and live or work in Yorkshire, UK.

6.2 Exclusion criteria

Children who pose a significant risk of harm to themselves 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. Study Procedures

7.1 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.

7.2 Screening and Eligibility Checks

Eligibility checks will be conducted by the research assistant (RA) 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 before informed consent/assent being obtained.

7.3 Incentives

Participating families will receive £20 worth of Love2Shop shopping vouchers at the end of their participation as an incentive and expression of gratitude for their time given to the study. They will receive the voucher via post after completing their final outcome measures. Families with more than one participating child will receive a £20 voucher for each child they complete the final outcome measures for.

7.4 Informed Consent

Participation in the study will be entirely voluntary and written informed consent (and assent where appropriate) from participants will be obtained before any involvement in data collection. Participants under the age of 16 will be invited to complete an assent form, but this will not be a mandatory requirement (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.

7.5 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.

7.6 Withdrawal Criteria

Any participant can withdraw from the study at any time without having to provide a reason for withdrawal. If one member of a parent-child 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 will remind participants that they do not have to provide a reason.

8. Study Intervention

8.1 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.

8.2 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.

8.3 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.

9. Statistics and Data Analysis

9.1 Sample Size Calculation

We will recruit 10 child-parent/guardian dyads (totalling 20 participants). 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.

9.2 Data Analysis

Data analysis 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.

10. Data handling

10.1 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.

10.2 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.

10.3 Data Sharing

Anonymised participant data will be made available on request. Requests should be made to the study research team 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.

10.4 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.

11. Safety and Risk

11.1 Assessment and Management of Risk

We do not anticipate that participants will be subject to any substantial risks during this phase of the study. However, the focus of this study is on nature-based and outdoor activities and, as such, usual risks associated with being outdoors may be expected including but not limited to slips, trips, falls, sunburn, insect bites, stings, etc. All children will be expected to be supervised by a parent/guardian or carer during the intervention, and this expectation and recommendation will be expressed in the intervention instructions.

Participants will be asked during the eligibility assessment if there are any risk concerns. Participants will be reminded in intervention materials to have any relevant medication including inhalers and emergency medication at hand. It will be the responsibility of the participants (or their attending parents) to manage and administer their own medications.

11.2 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

11.3 Collecting, Recording, and Reporting of Adverse Events

Participants will be encouraged to report any arising AEs and 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. 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.

12. 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.

13. Definition of End of Study

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

14. 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. Separate ethical approval will be sought for this user testing phase of the study, as covered in the present protocol.

14.1 Peer review

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

14.2 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 has been 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.

14.3 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.

14.4 Financial and competing interests

There are no financial or competing interests to report. Advice and guidance has been and will continue to be sought from Medipex in the creation and continuous development of the intervention. The research team do not intend to capitalise upon the designed intervention and wish for it to be publicly owned.

14.5 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.

14.6 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.

14.7 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 usual care throughout the duration of the study. Should any additional needs be identified through the study, 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.

15. Complaint Handling

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

16. 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.

17. References

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12. Protocol Amendment History

Amendment No.	Protocol version no.	Date	Author(s) of changes	Details of changes made