Protocol

Study Title: Forest school INterventions for Children's Health (FINCH): a feasibility cluster randomised control trial

Chief investigator: Dr Hannah Armitt and Professor Peter Coventry

Sponsor: Humber NHS Teaching Foundation Trust

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:			
Signature: 		Date: 20/10/2024	
Name (please print):..... Cathryn Hart.....			
Position: .....Assistant Director R&D.....			
Chief Investigator/s:			
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Names: (please print): Dr Hannah Armitt Professor Peter Coventry			

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STUDY SUMMARY

We aim to test if it is possible to run a randomised controlled trial of Forest School in primary schools in England. We want to learn if Forest School is acceptable to children and school professionals.

Study Title	**Forest school INterventions for Children's Health (FINCH): a feasibility cluster randomised control trial**
Internal ref. no. (or short title)	FINCH
Study Design	Mixed method design. - WP1 Feasibility RCT of a Forest School intervention - WP2 Process analysis. - WP3 Preliminary collection of health economic data. - WP4 Focus groups to refine the logic model and optimisation of the intervention.

Study Participants	Children aged 7-11 (KS2) in participating schools including those with special educational needs and/or physical disabilities.
Planned Size of Sample (if applicable)	8 schools: 4 intervention and 4 control assuming 25 children per school year group.
Follow up duration (if applicable)	24 weeks
Planned Study Period	22 months - September 2024 -June 2026
Research Question/Aim(s)	● Is Forest School an acceptable and feasible intervention to improve the mental health of KS2 children? ● Is it feasible to run a cluster Randomised Controlled Trial (RCT) of Forest School for children in key stage 2?
Outcome measures	Strengths and Difficulties Questionnaire (SDQ) Child Health Utility 9D (CHU 9D) School attendance Nature Connection Index (NCI) Inclusion of Nature in Self Scale (INS) Frequency of access and attitudes towards green and natural spaces The UK Habitat Classification (UKHab)
Key Terms	Forest School, Children and Adolescents, Education, Wellbeing, Mental Health, Families

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
National Institute for Health Research (NIHR)	**£ 535,816.15**

Roles and responsibilities of study steering group and patient and public involvement group

Trial Steering Group

A Trial steering group will be held every 6 months of the study. The trial steering group will be attended by the study leads in addition to independent academics with specialist knowledge of trial delivery and data management. The trial steering group will ensure the study runs to the study protocol.

Study Management Group

A study management group will be held every month during the 20 months of the study. The study management group is made up of public contributors, academic co-applicants and co-applicants from the education and local authority. The study management group will be responsible for ensuring the study runs to the protocol.

Patient & Public Involvement Group

Our Children and Young Person's (CYP) panel will include approximately 10 children (aged 7-12) and their parents/guardians. Children will have facilitated creative sessions separate to their parents with both groups then coming together at the end. Sessions are to be held in the 'roundhouse' at Rewilding Youth Hull to provide a green setting for activities. In line with NIHR guidance, and as suggested by the CYP, we will appropriately remunerate children and parents for their time using vouchers. We will hold eight sessions throughout the grant term with initial sessions focusing on providing training to young people on what research is and developing creative patient information sheets/initial communications. Six sessions will be undertaken when the research is up and running to share results and ask for feedback. Two sessions will be held at the end of the study to look at creative means of dissemination.

The opportunity to join the panel will be shared widely across a variety of platforms and services including but not limited to Humber teaching NHS FT (Youth Forum and Recovery College), Rewilding Youth Hull, Child Orientated Mental Health Innovation Collaborative (COMIC) PPI group, local authority contacts (MHST manager) and through local community groups meeting the needs of ethnically diverse communities.

In addition to the CYP and parent panel we will ensure we hold initial open sessions before beginning research at any school sites inviting all parents/guardians, teachers, staff and governors. We will ensure at each session delivered with schools/parents they are given brief training on the research protocols and involvement to ensure they feel their input is valued.

STUDY PROTOCOL

Forest school INterventions for Children's Health (FINCH): a feasibility cluster randomised control trial

1 BACKGROUND

There is a large body of research to suggest nature-based interventions can be an effective means of supporting CYP's mental health. Nature connectedness has been identified as a key concept with research showing that individuals who are more connected with nature are usually happier in life and more likely to report feeling their lives are worthwhile (Richardson & McEwan, 2018). Evidence suggests that COVID-19 has widened the inequality gap and children from ethnic minority backgrounds, and those from low income households are less likely than children in more affluent areas to experience the full benefits of access to nature and green space (Fyfe-Johnson et al, 2021).

Forest School is a nature-based intervention with educational, health and social benefits evidenced across systematic reviews for children and young people (Garden & Downes, 2021, Dabaja, 2022).. Forest School is an English name developed from a rich tradition of Scandinavian 'Friluftsliv', literally meaning free air life (Gelter, 2000). Within Scandinavia there are a variety of interventions developed from this ethos including 'skovegrupper' (forest or wood groups), 'naturbørnehaver' (nature kindergartens) and ordinary early years settings that use the outdoor area they have available. These approaches can be distinguished from outdoor education which often starts with an issue, agenda, or problem for the children to investigate. Forest school approaches are led by the child's interests, within a loose skills framework with an ethos summed up by one Forest School practitioner as "..we follow what the children point out first, and set challenges" (Grenier, 1999).

While Forest School intervention has been the subject of several recent systematic reviews (Garden & Downes, 2021, Dabaja, 2022), there have been no randomised controlled trials and evidence is limited in respect of the mental health benefits (Beresford, 2023). Sella et al (2023) reviewed the literature on mental wellbeing and preschool children, finding positive impacts in a wide range of variables that promote child health and development. However, they concluded that more evidence is needed, due to methodological weaknesses across the studies they reviewed. Tiplady and Menter (2020) highlighted the paucity of studies focusing on older children and carried out a small-scale study looking at the impact of a Forest School project on the emotional wellbeing of two groups of young people currently unable to access mainstream education in the UK due to severe anxiety and/or emotional, social and behavioural difficulties. This study highlighted that Forest School was effective at improving CYP's emotional wellbeing. The learner-led pedagogy was identified as a critical factor in allowing CYP to 'take what they need' from the process.

There are several training centres and packages offered through national bodies such as the Forest School Association (FSA), training through previously funded government partnerships such as Nature Friendly Schools and Local Authority offers such as the Creative Outdoor learning Award (COLA), all of which give teachers/professionals the skills to organise and deliver outdoor activities in line with the nature-based pedagogy of Forest School. Patient and Public Involvement work indicates schools are delivering Forest School in line with nature-based pedagogy principles and there is often a set structure regarding frequency, timings, and activities, however delivery is often not as prescriptive as some of the training providers outline i.e., Forest School Association. Therefore, despite widespread implementation, evidence about optimal delivery methods of Forest School and the impact on mental health and emotional wellbeing is scarce.

2 RATIONALE

Forest School is a complex intervention and there is no agreed model of transformational process or theory of change. Studies have highlighted some potential pathways to improvements in mental health and wellbeing including self-regulation, resilience, autonomy, agency, providing nurture, time, and space away from school as well as connection to the rest of nature (McCree et al, 2018). Our proposed programme allows for iterative cycles of testing and refinement of Forest School as an emotional health and wellbeing intervention in schools. In partnership with our PPI group/members/co-applicants and using current literature we have developed an initial logic model and underpinning programme theory to better understand likely mechanisms of action and pathways to impact on emotional health and mental wellbeing. We will seek to refine this model at the end of the study to provide a more cohesive framework for the mechanisms of action of Forest School as an emotional and mental health wellbeing intervention.

This study will generate new knowledge about the feasibility of running a definitive Forest School trial with Key Stage 2 (KS2) children aged between 7-11 with and without SEND. We will test acceptability and feasibility of delivery, assess feasibility of trial processes, and establish key parameters for effectiveness and cost-effectiveness. We will seek to produce a manualised toolkit informed by our process evaluation and qualitative work to support further research and implementation.

3 RESEARCH QUESTION/AIM(S)

- Is Forest School an acceptable and feasible intervention to improve the mental health of KS2 children?
- Is it feasible to run a cluster Randomised Controlled Trial (RCT) of Forest School for children in key stage 2?

3.1 Aims

1. Assess whether it is feasible to conduct a full-scale definitive trial of the acceptability, effectiveness, and cost-effectiveness of a school-based Forest School intervention on mental health among KS2 children.
2. Conduct a mixed methods process evaluation
3. Collect feasibility data to support an economic evaluation in a full trial
4. Refine the current logic model and optimise the intervention

3.2 Core objectives:

1. Test feasibility and acceptability of recruitment, randomisation strategy and trial procedures (WP1, WP2)
2. Estimate recruitment and retention rates (WP1)
3. Test feasibility of collecting health outcomes, process, and health economic measures (WP1, WP2, WP3).
4. Evaluate implementation and fidelity of delivery to determine feasibility of the intervention (WP2)
5. Evaluate the acceptability of the intervention from the perspectives of children, parents, Forest School Facilitators, and other professional stakeholders (WP2)
6. Explore contextual factors affecting implementation and mechanisms of impact (WP2)
7. Refine logic model developed prior to study commencement and programme theory to inform optimisation of intervention for definitive RCT (WP4)

4 Study design and methods of data collection and analysis

4.1 Study team

We have assembled a first-rate research team with a world class track record and reputation in delivery of mental health RCTs, environmental science, science education, mental health policy, knowledge translation and mobilisation, qualitative methodologies, health economic modelling, and public and patient involvement and engagement.

We have two experienced co-leads: **Prof Peter Coventry (co-PI)** is a mixed methods applied health scientist in the Department of Health Sciences at the University of York. He co-leads the Environment and Health research theme at the York Environmental Sustainability Institute (YESI). He leads an active portfolio of research on the mental health benefits of nature-based interventions (e.g., NIHR Yorkshire and Humber Applied Research Collaboration). **Dr Hannah Armitt (co-PI)** is an early career researcher and senior Clinical Psychologist who has extensive clinical experience working within child and adolescent mental health services in the neurodevelopmental speciality. Dr Armitt co-led the CONIFAS study (NIHR203043) which aimed to co-produce a nature-based intervention for children with ADHD. **Prof Catherine Hewitt** is a Professor of Statistics and Director of York Trials Unit. Her research portfolio is currently in excess of £50 million from a number of funders across different disciplinary boundaries including several NIHR programmes, charities and international sources. Catherine is Chair of the NIHR HTA general committee. Other co-applicants include;

- **Prof Bernadka Dubicka** a child and adolescent psychiatrist and research lead for Health Innovation Manchester,
- **Prof Piran White** Professor of Environmental Management in the Department of Environment and Geography.
- **Prof Susan Griffin** is a Professor of Health Economics in the Centre for Health Economics, University of York.
- **Dr Sarah Blower** is a mixed methods researcher and Assistant Professor of Child Development and Family Wellbeing in the Department of Health Sciences, University of York.
- **Ellen Kingsley** is an experienced researcher who has coordinated multiple child mental health focused NIHR studies. Ellen was recently trial coordinator on the CONIFAS study (NIHR203043) utilising specialist skills in co production when working with nature based interventions.
- **Mike Foers** is a Senior Community Integration & Transformation Manager for Children and Young People in Hull at Humber and North Yorkshire Health and Care Partnership.

We have two experienced PPI Leads on the research team. The PPI Lead role will include developing and shaping the PPI plans with public contributors including our collaborators Re-Wilding Hull and setting and refining overall PPI strategy as the project progresses.

- **Angela Kingston (AK)** is the mother of four children, two of whom are neurodiverse young people. AK has experience of working as a Governor of three schools supporting safeguarding, Looked after Children and Special Educational Needs and Disabilities (SEND).
- **Marnie Palmer (MP)** is an experienced teacher in a special educational needs school and is a qualified forest school practitioner regularly delivering sessions.

Collaborators include individuals with specific expertise in delivering Forest School and supporting children and young people.

- **Ms Sara Booth-Card** (Yorkshire Wildlife Trust) has a breadth of knowledge engaging children and young people with the environment. Sara works for the Nature Friendly Schools Project with links to Young Minds
- **Cindy Stephenson** is an experienced Forest School practitioner and Chief Executive of Humber Forest School. Cindy has excellent relationships with local schools as well as an in-

depth knowledge of running and supporting the delivery of Forest Schools and outdoor based activities with children.

- **Dr Charlotte Dean** is a researcher and youth worker at Rewilding Youth who specialises in facilitating creative and collaborative research projects using methods such as Citizen Inquiry and Participatory Action Research with children and young people.She will support the PPI delivery and Re-wilding Youth Hull can provide a venue for PPI activity to take place in.

4.2 Study design

The research will have four interconnected work packages with a mixed method design. In WP1 we will carry out a feasibility RCT of a Forest School intervention with 250 children in 8 schools across Hull, East Yorkshire, and North Yorkshire. In WP2 we will evaluate the quality and fidelity of intervention delivery through a process analysis. WP3 will focus on preliminary collection of health economic data. WP4 will use focus groups to refine the logic model and optimisation of the intervention.

4.3. Study setting and sites

The study is a multi-site study taking place in 8 primary schools across East and North Yorkshire. We will work with each school to select a Key Stage 2 class to be part of the study. This decision will be made by the teachers based on the practicality of delivery. If reasonably possible we will ensure we have a range of Key Stage 2 classes (Years 3-6) to ensure variation in age groups. All children in the class will be invited to take part ensuring equal access.

4.4. Study population

Children aged 7-11 (KS2) in participating schools including those with special educational needs and/or physical disabilities. PPI work with schoolteachers indicates Forest School is an inclusive intervention that can be adapted to children's needs, providing examples of children using wheelchairs, children with Cerebral Palsy and children with complex physical and learning needs who are able to take part. We will use a school study agreement and consent form with each school to clearly delineate requirements for participation and hold an introductory meeting prior to commencing.

Inclusion criteria

- Schools with existing capacity and training to deliver Forest School as defined in the study intervention
- Outdoor space available within school grounds
- All Key stage 2 children within the specified class

Exclusion criteria

- As this is a feasibility study, we will not exclude schools unless they have no access to outdoor space of any type and are not practically able to run Forest School. We are keen to test feasibility of delivery across a variety of habitats in recognition that this improves accessibility and diversity.

4.5. Recruitment and consent procedures

We will gather expressions of interest (EOI's) from across schools, including those schools we have already contacted in the development of the application, and will look to purposively sample schools to include a range of geographic regions situated within communities with differing levels of social economic deprivation, ethnically diverse communities and with varying access to outdoor space to undertake Forest School. A poster and patient information sheet will be available to schools and this

will be shared across email, social media platforms including X and physically within meetings and with schools.

Once a school has officially joined the study they will sign a school study agreement which will set out the study timescales and protocol requirements . The school will select the Key Stage 2 class that is most suitable practically to take part in the intervention. All children in this class will then be invited to be part of the study using a child friendly participant information sheet (developed with PPI) and a parent information sheet.

Opt out criteria will be used for the feasibility study. Parents or guardians will be provided with the patient information sheet and contact details for the study and given the option to opt out of data collection. Parents/carers will be asked to return a signed 'Parent/Carer Child Withdrawal' form if they do not wish to share their child/children's data with the research team and/or they do not wish themselves or their child/children to take part in any assessments or surveys and subsequent focus groups and interviews. The research team and the school will then remove the respective parent and child/children from any follow-up assessments or communication about the study. This will not affect their child's participation in the Forest School.

A consent form will be used for the qualitative research interviews. Consent will not be taken for the observations.

4.6. Sample size

The sample size calculations are based on estimating retention rates and standard deviation (SD) of the candidate primary outcome (SDQ). At least four clusters per group are recommended for cluster pilot RCTs and we intend to randomise 8 Schools. An average of 25 children per school is anticipated and we will include eight schools (i.e. 200 children). This will be equivalent to 70 children in an individually randomised trial (assuming an ICC of 0.1) and would be sufficient to allow completion rate of 80% to be estimated within a 95% confidence interval of ±9% and is in line with sample size for estimating a reliable SD. We will recruit additional schools to go on a reserve list in case schools drop out before randomisation or before they start delivery of Forest School.

4.7. Baseline assessment

Demographic information for children will be taken at baseline alongside primary and secondary outcome measures. This information will be provided by the school from their routinely collected data. These data will include: age; gender (male/female/third gender); ethnicity; special educational needs and disabilities (children with Education Health Care Plan; existing diagnoses), if in receipt of free school meals, pupil premium, and postcode of the child's registered address. We are collecting this to find out if the intervention is accessible for a diverse population.

Demographics for parents will be collected using a short demographic questionnaire based on questions from the Office of National Statistics (ONS). This questionnaire will be given to parents to complete and return to the school for collection by the research team or to the research team directly through a self addressed envelope. This information will be: age, gender, ethnicity, marital status, relationship to the child involved in the study, highest level of academic qualification, occupation, and accommodation status.

4.8. Randomisation

Schools will be randomised with a 1:1 allocation ratio by a statistician based in York Trials Unit (YTU) who is not involved with the recruitment of the schools. Minimisation using free school status (at or

above national average/below), class (year 3 or 4/ year 5 or 6) and location (urban/rural) will be undertaken using MinimPY software.

4.9. Intervention arm (Forest School intervention)

Definition: The intervention can be described as 'A non-classroom based timetabled session of child-led exploration and play in an outside space encouraging connection with and exploration within nature'. We have used existing best practice and definitions looking at current models of Forest School delivery within schools (Forest School Association (FSA), Nature Friendly Schools, Creative Outdoor Learning Award (COLA) and PPI input (PPI Leads/workshops/schools) to define what Forest School means in the context of this feasibility study. We have defined minimum standards that all schools must ensure are included as part of Forest School sessions:

1. A non-classroom, child-led experience.
2. Outdoor space with natural features, room for forming a circle, and materials such as rope, various tools, and natural materials like leaves and twigs.
3. Encouragement of connection with and exploration of nature through activities. This encompasses sensory contact with the natural world, fostering an emotional bond with and love for nature, appreciating the beauty of nature, contemplating the meaning and signs of nature, and demonstrating compassion and care for nature.

Rationale and goals of the FINCH intervention

The intervention will be underpinned by existing and established frameworks around Forest School that characterise seven core areas related to: fire skills, using tools, navigation, cooking and growing food, den building and knots, nature appreciation, and personal and social skills. Within these core skill areas, participants will be given opportunities to explore specific activities with the Forest School lead teacher and assistant adapting these to the learners' interests, abilities and needs. Examples may include supporting a child with fine motor skill difficulties to use tools or providing modifications to an activity such as a quiet space for a child to work away from the group. Sessions are not prescriptive but do need to include the core skill areas across the school term of delivery in order that there is adherence to minimum standards (see below).

Materials and mode of delivery

Our collaborators, PPI work and existing Forest School delivery principles informed the development of this section. They have significant experience of the practical application of these principles. Sessions will take place for at least two timetabled hours each week for one term (Spring/Summer) which equates to 12 sessions. A minimum of 10 out of the 12 sessions need to be delivered, allowing for unforeseen circumstances such as staff illness. Splitting sessions into shorter time frames to account for unforeseen circumstances will also be considered appropriate i.e., 2 x 1-hour lessons instead of 1 x 2-hour session. Sessions will be delivered by existing staff within schools (headteachers, teachers, teaching assistants) who have previously received a specific core level of relevant training in Forest School delivery including FSA Level 3, Nature Friendly Schools training, COLA, and/or at least 5 years' experience in delivering nature/outdoor based play/learning to account for skilled individuals with backgrounds such as Brownies/Scouts. Although we intend this to be an inclusive feasibility study, PPI work has indicated a school with no previous experience of delivering any form of outdoor or nature-based intervention would find it difficult to deliver Forest School intervention from no knowledge base. We need to balance the desire to be inclusive with the practicalities of running a small feasibility cluster RCT.

There will be a minimum adult to child ratio of 1:9 and those with SEND will be supported by teaching assistants and additional classroom capacity through volunteers. We will run a call for volunteers at our initial open sessions at each school to provide an opportunity for continuing professional development for existing staff such as midday supervisors and parents to potentially volunteer within the intervention sessions to increase the adult child ratio.

4.10. Control arm

Whilst the intervention schools are offered Forest School, the control schools will be undertaking usual indoor classroom-based curriculum activity.

4.11. Outcome measures and data collection

Primary outcome

Strengths and Difficulties Questionnaire (SDQ) : A candidate primary outcome for a definitive trial is the SDQ (Goodman, 1997) (parent and teacher versions). The SDQ is a brief emotional and behavioural questionnaire. The SDQ queries positive and negative attributes displayed by the child across five subscales: Emotional Symptoms, Conduct Problems, Hyperactivity/Inattention, Peer Relationship Problems, and Prosocial behaviour. A total score can also be generated by summing the first four subscales. The SDQ is regularly used in clinical practice and research and can be used alongside the Child Health Utility 9D in health economic evaluation.

This measure will be completed by parent/carer and teacher with research assistant support where needed.

Secondary outcomes

Child Health Utility 9D (CHU 9D): This measure will be completed by the child with parental and research assistant support. The CHU9D **(**Ferber & Segal, 2015) is a paediatric preference-based measure of health-related quality of life suitable for 7- to 17-year-olds. It consists of a short questionnaire and a set of preference weights using general population values. The questionnaire has 9 questions with 5 response levels per question and is self-completed by the child (or proxy completed for younger children).

Frequency of access and attitudes towards green and natural spaces: We will use a selection of questions from the People and Nature Surveys for England to help us gather information on parental attitudes towards green space and how often they access green spaces with their children. This will be completed by parents only.

Nature Connection Index (NCI): Nature connectedness is a psychological construct linked to both human well-being and pro-environmental behaviours. The Nature Connection Index (Richardson et al, 2019) can be used with adults and children to identify changes in nature connectedness for individuals and groups of people. Nature connection is a key underlying theory as to why Forest Schools may be effective and so could be important to measure in a future definitive trial. This measure will be completed by children.

Inclusion of Nature in Self Scales (INS) asks respondents to select one of seven pictures that best describes their relationship with the natural environment. This will be used alongside the NCI for children only (Schultz, 2001).

School attendance: Attendance for the Forest School intervention will be collected from school attendance registers. This will include specific data on Forest School session attendance as well as overall school attendance for the entire term.

Contextual measures

The UK Habitat Classification* (*UKHab): UKHab (2023) is a free-to-use, unified and comprehensive approach to classifying habitats which is flexible enough for use in a wide range of habitat survey types including small urban sites. The UKHab will be used to record the school outdoor environment delivery takes place in. The feasibility study is interested in whether this information can be collected and whether type of school habitat impacts on delivery. This measure is collected by the research team at initial site visits.

***Local Environmental Context*:** In order to understand the local environmental context of a school, we will use existing online data tools. We will use Natural England's Green Infrastructure map to identify accessible blue and green infrastructure and woodland around schools, as well as play and active recreation facilities and the public rights of way and access points that connect these spaces to their surroundings. This tool also provides a visualisation of the Accessible Greenspace Standards for England, shown as buffers calculated according to distance from greenspaces of different minimum sizes. The environmental context of a school that is relevant to the health and wellbeing of children extends beyond green and blue space, so we will also include other environmental factors such as air and noise pollution, which will be obtained from the SHAPE Atlas.

If appropriate, we will also consider including high-resolution data from the Urban Atlas from Copernicus, such as the urban green areas layer, although the most recent data for the UK in the Urban Atlas are from 2018. For each school, we will use spatial analysis to present the relevant datasets at high resolution within buffer zones around the school buildings. This will include a 1 km buffer, which aligns with the Green Infrastructure Standards recommendation that everyone should have access to and benefit from good quality green and blue spaces within 15 minutes' walk from home, and also larger buffers such as 3km and/or 5km.

Forest School Facilitator Checklist: Brief self-report checklists to be completed by the lead Forest School Facilitator after each session. The checklists will capture date and time of the session, number of pupils in attendance, number of staff in attendance, location, focus of session (linked to core principles), activities delivered, details of any tailoring or adaptation to activities, level of enjoyment and engagement from learners, facilitator satisfaction, and a free text box to capture any other notes/comments.

Table of outcome measures and timepoints

	Baseline	Follow up (12-13 weeks)	24 weeks	After each intervention session	End of term
School					
Child Demographics	X				
Resource use questionnaire; school	X				
Attendance					x
Teacher					

Strengths and Difficulties Questionnaire (SDQ)	x	x	x		
Resource use questionnaire; teacher	X				
Forest School facilitator checklist				x	
Parent					
Demographics	X				
Strengths and Difficulties Questionnaire	x	x	x		
Frequency of access and attitudes to green space	x	x	x		
Child					
Child Health Utility 9D (CHU 9D)	x	x	x		
Nature Connection Index (NCI)	x	x	x		
Inclusion of Nature in Self Scale (INS)	x	x	x		

Health resource use

This work package (embedded in WP1) will focus on the feasibility of collecting data to support an economic evaluation that would reflect costs and relevant outcomes from a health and education perspective. For health outcomes we will assess completeness and response rates to the Child Health Utility 9D (CHU 9D) across subgroups (no SEND, SEND type), and compare this to the potential of using SDQ data mapped to health-related quality of life in terms of completeness and in terms of any additional uncertainty introduced by the use of a mapping algorithm (Boyer, et al 2016). This will

inform the trade off in a full trial between questionnaire burden (both CHU 9D and SDQ vs SDQ alone) and quality of data on child mental health impacts. CHU 9D or SDQ mapped to CHU 9D is anticipated to capture any immediate impact of Forest school on child mental health.

Improvements in SDQ may be used to predict improvements in child mental health, which in a full economic evaluation could be used to predict ongoing health-related quality of life and health resource use (Goodman & Goodman, 2011). The feasibility of collecting SDQ and attendance will inform the choice of educational outcomes in a full economic analysis that would accompany a full trial.

For the education sector cost perspective, we will develop resource use questionnaires (school questionnaire, staff questionnaire) and apply them in participating schools to determine whether it is feasible to identify any change in resource use from delivering Forest School in different school settings compared to usual activities (no Forest School). Within this we will assess the impact on total school resources used to make activities accessible and inclusive to children with SEND (school questionnaire). The school questionnaire will aim to identify expenditure on infrastructure and equipment. A staff questionnaire for individuals running the forest school sessions will assess staff time in planning and delivery of the intervention.The school questionnaire will include staff time spent in training and the community of practice, and we will also examine costs that would be charged to the school for training workshops and any attendant materials.

Resource use questionnaires *(school questionnaire, staff questionnaire):* To assess the impact on total school resources used. To look at additional resource use to make activities accessible and inclusive to children with SEND (school questionnaire) and assess staff time in planning and delivery of the intervention alongside scalability.

Data collection

Parent questionnaires will be distributed by the school, either sent by post or handed directly to parents or via children to pass on to their parents. Parents are asked to complete their questionnaires as soon as possible after receiving them and should not include their own or their child's name on the form. Completed questionnaires can be returned in one of two ways: directly to the research team using the provided pre-paid envelope, or via the child’s teacher to be returned to the school.

Child questionnaires will be completed in the classroom, under the supervision of a researcher from the University of York or Humber NHS Trust. Pupil details (such as attendance, demographics, and class teachers) will be collected by the school and provided using a spreadsheet, with submission via a University of York approved and secure online drop-off service.

Additionally, the school will complete a paper-based resource use questionnaire. Class teachers will be asked to complete two questionnaires and a checklist on paper. All questionnaires (parent, child, school, and teacher) will be stored together in a locked box by the school, for collection by the research team

Trial processes

We will collect feasibility data to inform a future randomised controlled trial of Forest School. In addition, we will collect primary and secondary outcome measures at 3 timepoints, (baseline); initial follow-up (week 12); and final follow up (week 24) for both groups (see flow diagram). The research assistant will support the facilitation of these measures remotely, by telephone or face to face depending on preference of parents and teaching staff. PPI work has informed the selection of measures and key considerations such as parental burden and accessibility have been considered.

- ***Recruitment:*** how can we successfully recruit to the study, what is the best way to engage with the population, which school sites are involved
- ***Retention:*** Do schools and participants withdraw from the study, if so, why and how can we reduce the number of withdrawals
- ***Representativeness of participants***: we will collect demographic information to determine if the intervention is accessible for a diverse population. Age; gender (male/female/third gender); ethnicity (based on ONS categories); special educational needs and disabilities (children with EHC; diagnosis); Index of Multiple Deprivation based on participant home postcode.
- ***Data completeness:*** Do schools and CYP complete the outcome measures included.
- ***Acceptability of trial processes and intervention:*** This relates to both the intervention and the research process and will be assessed based on quantitative data of the school sessions carried out and qualitative interviews with participants.

Progression criteria for a definitive RCT will be based on a RAG-rating traffic light system of green (proceed to RCT), amber (review RCT design and/or intervention components and delivery); and red (stop and reconsider the design and/or intervention components and delivery)

Criteria	Green	Amber	Red
Recruitment			
Number of clusters recruited	7	<7 to ≥5	<5
Proportion of clusters recruiting a minimum of 15 participants	100%	<100% to ≥60%	<60%
Acceptability of intervention delivery			
Proportion of participants starting the intervention	≥80%	<80% to ≥50%	<50%
Proportion of participants completing all intervention sessions	≥75%	<75% to ≥50%	<50%
Data Completeness			
Completion of the primary outcome – Strengths and Difficulties Questionnaire	≥80%	<80% to ≥65%	<65%

4.12. Quantitative Data Analysis

Descriptive statistics will summarise quantitative data on implementation and fidelity (to include means, standard deviations, frequencies, and percentages as appropriate). Data on the numbers of schools and pupils approached, agreeing to participate, schools randomly assigned, schools receiving intended intervention, completing the study protocol, and pupils providing outcome data will be summarised. The number of schools/pupils withdrawing from the trial, and where available, the reasons for withdrawal, will be summarised. For each data collection point the number of non-responders will be calculated and participation rates compared. We may also quantify the degree of clustering using ICCs (with 95% confidence intervals) but acknowledge that this may not be reliable due to the small sample size (Eldridge et al, 2015). All data will be summarised descriptively as counts and percentages for categorical data and means, SDs, median, minimum, and maximum for continuous data. Data will be summarised descriptively overall, by group and within subgroups (SEND status/type). We will gather this data on SEND status to consider whether it will be feasible and useful to examine subcategories for a future full trial. The number of sessions delivered and attended will be summarised as a measure of acceptability.

We will consider qualitative alongside quantitative process evaluation findings to make an overall assessment of the acceptability and feasibility of the intervention. The analysis will inform the optimisation of intervention components and refine understanding about mechanisms of action to support further logic modelling in readiness for testing effectiveness in a definitive trial (see WP4).

5 Process Evaluation

Our process evaluation is informed by existing frameworks (Skivington et al, 2021, Moore et al, 2015, May, 2013) and draws on mixed methods to examine the feasibility and acceptability of the intervention and mechanisms of impact.

5.1 Patterns of implementation and fidelity

The process evaluation will gather data to establish how the intervention is delivered and whether this varies across schools (objective 4). The intervention is flexible with scope for adaptation by school staff to suit the needs of learners and context of delivery. Nevertheless, there are several core principles and minimum standards that must be adhered to in order to meet our definition of Forest School (see Planned Intervention section). We will explore *adherence* to these principles via Forest School facilitator brief self-report checklists to be completed by the lead Forest School Facilitator after each session. The checklists will capture: date and time of the session, number of pupils in attendance, number of staff in attendance, location, focus of session (linked to core principles), activities delivered, details of any tailoring or adaptation to activities, level of enjoyment and engagement from learners, facilitator satisfaction, the extent to which the session was child led, amount of time spent outside and a free text box to capture any other notes/comments.

5.2 Quality of delivery and participant responsiveness; observations

Quality of delivery and participant responsiveness will be assessed in a structured observation conducted by a member of the research team in two randomly selected Forest School sessions. We will develop a coding framework for the structured observation in line with specialist guidance on implementation and process evaluation of school-based interventions in school settings (Lendrum & Humphrey, 2012). Items will be developed to code indicators of quality of delivery, for example facilitator interest and enthusiasm, preparedness, clarity of expression, and participant responsiveness during the delivery of a session (Humphrey et al, 2016). Items coded to assess participant responsiveness will assess the extent to which pupils appear to be engaged and interested in the intervention materials and activities. We will consult with our PPI and advisory groups on the development of the coding framework.

We will establish *reach* and *dose* by using attendance registers and session facilitator checklists to determine the number and proportion of children who engage in at least one activity in at least four of the seven core Forest School areas and monitoring the overall number of sessions delivered per school.

Qualitative interviews with one teacher of a control school will explore the extent to which Forest School is different from existing provision (*differentiation*). We will also interview intervention group teachers, see below for more detail including interview methods.

5.3 Semi-structured interviews: Acceptability, context and mechanisms of action

Qualitative data will be generated via semi-structured interviews. We will purposively sample and recruit interviewees representing the following stakeholder groups: Forest School facilitators (n=8), wider school staff (n=8), children and their parents (n=16 dyads). Sampling of Forest School Facilitators (1 per school) will be informed by implementation data to ensure we capture the views of

high/low fidelity facilitators. Wider school staff will be sampled to provide a range of seniority and role to include head teachers and teaching assistants or SEND staff. Children and parents (2 dyads per school) will be purposively sampled to generate variation in age, gender, socio-demographic group, school, and SEND status.

Topic guides will be used to focus discussions and emergent/unforeseen issues will be explored as appropriate. Topics covered in the guide will include perspectives on the acceptability of Forest School; how and why the intervention might impact on child outcomes and perspectives on whether the impact achieved is influenced by student characteristics, wider school contexts or other factors; any unintended, potentially harmful consequences; and the acceptability of collecting measures and trial processes. Separate topic guides will be created for each stakeholder group and will be informed by the Theoretical Framework of Acceptability (TFA) (Sekhon et al, 2017), developed in consultation with our PPI and advisory groups.

Interviews will be conducted in person (in school) or online, depending on the preference of the interviewees. All interviews will be audio-recorded and transcribed verbatim. Topic guides and interview procedures will be piloted prior to use and refined as needed. Quantitative data on the context for delivery will be gathered via UKHab, while factors that are anticipated to affect engagement with and benefits of Forest School will be captured using the NCI and the outdoor learning skills progression tool. Collecting these data will allow us to pilot mediator analyses representing theorised mechanisms of action.

5.4 Qualitative analysis

Qualitative data will be uploaded into specialist software to be analysed via qualitative content analysis (free text from checklists) and thematic analysis (interview data) following the steps outlined by Braun et al (2023). Findings will be sensitised to the TFA and context-mechanism-outcome configurations will be developed.

5.5 Logic model refinement and intervention optimisation (objective 7)

Data from the process evaluation will be used to deepen understanding about mechanisms of action, reach consensus about the core intervention components, and establish ways to optimise delivery in schools in a large trial. We will run three facilitated workshops to support rapid cycles of analysis and feedback about the acceptability and feasibility of the intervention. Workshop participants will be the research team, including PPI co-applicants, and Forest School consultant CS. In workshop 1 analysed data from observations and interviews from WP2 will be organised, filtered, and interpreted using affinity sorting and diagramming to cluster key findings and prioritise next steps (GOV.UK, 2018). In workshop 2 participants will refine the intervention programme theory and logic model developed prior to the study start (to include consideration of any potential harms or dark logic) to inform the evaluation framework to be used in a definitive trial. In workshop 3 participants will use the TIDier checklist to identify and characterise core intervention components and features to be carried forward into the main trial (Hoffman et al, 2014). Co-applicants MP, AK and Forest School consultant CS, will ensure that the intervention is refined within agreed limits and capabilities of primary schools.

6. Ethical and regulatory concerns

This study will be conducted in accordance with ICH Good Clinical Practice guidelines. Ethical approval has been sought and approved from the Department of Environment and Geography Research Ethics Committee (REC).

The study involves asking participants to allocate time to answering questions using questionnaires and interviews. We will minimise the burden on participants by providing different ways for them to complete the questionnaires (via phone/pen and paper) at times which are convenient to participants. Should participants have additional needs such as literacy difficulties we will support participants to complete the questionnaires.

6.1 Assessment and management of risk

An adverse event is any unexpected effect or untoward clinical event affecting the participant (i.e.any unfavourable and unintended sign, symptom or disease). It can be directly related, possibly related or completely unrelated to the intervention. The severities of these events are outlined below:

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 behavioural incidents including:

- 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

Teaching staff will monitor children using internal school procedures for safeguarding and risk and any concerns arising because of the study will be communicated to the PI and research team as soon as reasonably practicable.

If participants have any issues, they will have contact details for the research team. We will put in place adaptations to ensure accessibility for those attending with disabilities such as sensory impairment or mobility restrictions. We will develop a resource pack for mental health support for schools which they signpost to if needed e.g., appropriate charities and local CAMHS.

6.2 Research Ethics Committee (REC) and other Regulatory review & reports

A favourable opinion has been granted from The Department of Environment and Geography REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements. The reference is DEGERC/Res/12072024/1.

Regulatory Review & Compliance

Before any site can enrol participants into the study, the Chief Investigators will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

Amendments

All study amendments will be approved by the study lead and all substantial amendments will be approved by the study lead, the Sponsor, and the TSC prior to submission to the REC. Amendment history will be tracked by adopting version control and via an amendment log. Amendments will be notified to participating sites.

6.3 Peer review

This study has been peer reviewed in line with the National Institute for Health Research (NIHR) Public Health Research (PHR) funding process.

6.4 Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach. These deviations or frequent breaches will be reported to the NIHR.

6.5 Data protection and patient confidentiality

In line with the 2018 General Data Protection Regulation and the UK Policy Framework for Health and Social Care,79 anonymised trial data will be securely archived by the University of York for a minimum of 10 years. Personal data of participants will be stored for up to three years after the study has ended for the purpose of disseminating study findings. It is unlikely that this will take longer than 12 months; however, to ensure that participants receive adequate and full information about the study after it has finished, additional time has been allocated.

All information collected during the trial will be kept strictly confidential as detailed above. Information will be held securely in paper and/or electronic formats at the University of York. The University of York complies with all aspects of the 2018 General Data Protection Regulation and Data Protection Act 2018. Operationally this will include obtaining explicit consent from study participants to record personal details including name, postal and email address, and contact telephone numbers; and appropriate storage, restricted access and disposal arrangements for their personal details. All participants will be informed of their rights in regard to the personal information stored, including erasure, rectification and objection. All work will be conducted following the University of York's data protection guidance which is publicly available (University of York, 2018).

6.6 Indemnity

Humber Teaching NHS Foundation Trust will act as the main Sponsor for this study and oversee the delivery of the study with York Trials Unit. Humber Teaching NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study to meet the potential legal liability of the sponsor for harm to participants arising from the management of the research. University of York holds negligent harm and non-negligent harm insurance policies which apply to this study and the involvement of York Trials unit for harm to participants arising from the design of the research.

The risk exposures under the study would fall under our combined employer's and public liability insurance cover which would respond to a claim. Delegated responsibilities will be assigned to the Local Authority Schools taking part in this study.The school's standard public liability insurance policy would cover any activity which is carried out by the school staff, including delivery of Forest School activities in line with the FINCH study protocol.

A suitable risk assessment must be in place to cover all elements of the activities being undertaken, with suitably trained staff present and with adequate supervision.

6.7 Access to the final study dataset

Anonymised participant data will be made available on request following consideration by the study team on a case-by-case basis. Requests should be made to the main trial contact and will be considered by the study management group which includes the study lead and co-applicants.

7 Dissemination

7.1 Dissemination policy

The data arising from the study will be owned by the sponsor Humber Teaching NHS Foundation Trust and The University of York under the terms set out in the collaboration agreement. On completion of the study the data will be analysed and a final study report will be prepared. The findings of the study will be published in an open access journal under the NIHR publication terms.

The main outcomes of the study will be

- Manualised toolkit: We will seek to produce a manualised toolkit informed by the interconnected work packages to inform further research and implementation. The toolkit will be an accessible, action orientated document including Forest School information, resources and tools compiled throughout the study.
- Protocol documents for progression to a full trial
- Accessible presentations, an online workshop with interactive elements and a newsletter. Producing a set of easy read infographics and creative outputs (video/social media).

As the study progresses we will create and share newsletter posts and social media content.

Our co-applicants come from a wide range of backgrounds, and we intend to utilise their networks to ensure good coverage across health, education, and social care nationally. Co-applicant BD is a fellow of the Royal College of Psychiatrists (RCPsych) and can provide dissemination opportunities at conferences, webinars and events. BD is also a board member for the Association of Child and Adolescent Mental Health (ACAMH) who can provide educational material about the study for dissemination. We will also disseminate the results through school organisations such as the National Association of Head Teachers who have previously worked with ACAMH in this capacity. Co-applicant SBC works for The Wildlife Trust and can provide opportunities to share findings in newsletters, online webinars and across social media. We have linked to the community of practice for the Mental Health Support Team's nationally on the 'Futures Platform' through the Quality Improvement Lead for Children and Young People's Mental Health (NHS England, North East and Yorkshire) and will have the chance to promote the findings through online forums, national and regional MHST newsletters, learning and development and conferences. We have strong links to our local Integrated Care Board and we have developed contacts within the Department of Health through the Innovation, Research and Improvement System (IRIS).

7.2 Authorship eligibility guidelines and any intended use of professional writers

All co-applicants and collaborators will be named on final publications as long as they meet the journal's guidance on contributing to paper authorship. The final study reports will have the study leads as corresponding authors.

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9 Appendices

9.1 Appendix 1- Required documentation

- Participant information sheets: School, parent, child
- Poster for study
- Consent for interviews
- Research team CV's
- Headteacher/Senior Leader information sheet and consent form for schools

9.2 Appendix 2 – Schedule of Procedures

Phase	Task	Description	Spring term Cohort 1	Summer term cohort 2
Phase 1 - Preparation	**1. Sign school study agreement consent form**	Document to be signed and returned by email to the FINCH team.	By December 2024	By March 2025
	2. Identify staff and select classes of pupils	Schools will identify relevant members of staff and select classes of pupils to participate in FINCH	By December 2024	By March 2025
	3. Arrange parent/governor information session	The FINCH team will arrange either an online or in person session at which information about the study can be shared to parents, governors and other interested parties	By December 2024	By March 2025
	4. Identify KS2 class to FINCH team	Schools will share lists of the identified staff members and pupils in selected classes with the FINCH team.	By December 2024	By March 2025
	5. Send information to parents/carers of pupils in selected classes	Schools will send out information sheets (provided by the FINCH team). This will include a broad outline of the project and opt-out forms for parents to return directly to us.	By start of January 2025	By start of April 2025
Phase 2 - Baseline Data Collection	**1. Complete the baseline outcome measures**	Teachers will complete the baseline measures identified above including SDQ . The FINCH research team can support this process.	January 2025 pre delivery	March 2025
	2. FINCH team to complete baseline measures with parents and children	The FINCH team will arrange with parents and children to complete the outcome measures identified for them including for, nature connectedness scale, Inclusion of nature and self Scales (INS) and Child Health Utility (CHU9D) for children. Parents complete the SDQ and questionnaire looking at frequency of access to green space and attitudes the same measures as teachers.	January 2025	March 2025
Phase 3 **Delivery of Forest School intervention**	**1. Forest School delivery for intervention group**	Begin delivery of 10-12 timetabled 2 hour Forest School sessions to Key Stage 2 class if in intervention group. If in control group education as usual for Key Stage 2 class.	January 2025-March 2025	April 2025-June 2025

or control group period	**2. Observations**	The research team will identify 2 Forest School sessions at random to observe across the 10-12 week period of delivery.	By end March 2025	By end June 2025
	3. All participants offered chance to take part in qualitative interviews	The research team will seek to interview 16 family dyads (parent/child) and 8 teachers from across the intervention and control groups	By end September 2025	By end September 2025
	4. Mapping of school environment and surrounding green space	Research team to use tools such as the UK Habitat classification system to map green space in school grounds and surrounding area	By end September 2025	By end September 2025
Phase 4 **Follow up outcome measures at end of intervention period**	**1. Complete the follow up outcome measures**	Follow up outcome measures to be completed by teachers for all pupils in selected KS2 class taking part in study.	By April 2025	By July 25
	2. Research team to complete 6 month follow up with parents/children	Follow up outcome measures to be completed by research team for all parents/children in study	By April 2025	By July 2025
6 month follow up data collection	**1. Complete 6 month follow up questionnaires**	Teachers to complete 6 month follow up questionnaires	By September 2025	By December 2025
	2. Research team to complete 6 month follow up with parents/children	Research Team to complete 6 month follow up questionnaires	January – March 2025	By December 2025
	3. Provide attendance data for the school year for pupils taking part in study	School to provide attendance data to research team.	By September 2025	By September 2025
Dissemination	**1. Reports produced from study to share with schools and end of study events**	FINCH team to liaise with school about best means of disseminating reports.	By July 2026	By July 2026

9.3 Appendix 3 – Amendment History

Version	Date	Editor	Comments
1.1	25.06.2024	Hannah Armitt and Professor Pete Coventry	
1.2	29/07/2024	Hannah Armitt	Removed reference to Memorandum of understanding and changed to school study agreement and consent form
1.3	21/08/2024	Saddaf Shaheen	Indemnity information added and protocol reviewed
2.0	17/10/2024	Hannah Armitt/Pete Coventry/Jodi Pervin and Rachel Bottomley-Wise	Baseline measures changed and additional information around data collection added