NHS
Health Research Authority

Evaluation of the Outdoor Play and Learning (OPAL) programme on the mental health of primary-aged children in England, a feasibility Randomised Controlled Trial

Version 1.2 January 2024

Project Playtime

TRIAL REGISTRY NUMBER AND DATE

TBC

PROTOCOL VERSION NUMBER AND DATE

Version 1.2, 16/01/2024

OTHER RESEARCH REFERENCE NUMBERS

Funder reference - MR/S017909/1

SPONSOR / CO-SPONSORS / JOINT-SPONSORS

University of Exeter

Project Playtime

FULL/LONG TITLE OF THE TRIAL

Evaluation of the Outdoor Play and Learning (OPAL) programme on the mental health of primary-aged children in England, a feasibility Randomised Controlled Trial

SHORT TRIAL TITLE / ACRONYM

Project Playtime

PROTOCOL VERSION NUMBER AND DATE

- Version 1.2

Project Playtime

RESEARCH REFERENCE NUMBERS

IRAS Number:	333480
EudraCT Number:	Not applicable
ISRCTN Number / Clinical trials.gov Number:	. To be added in
SPONSORS Number:	
FUNDERS Number:	MR/S017909/1

Project Playtime

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol.

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

Chief Investigator:

Date: 16/1/24

Signature: 

.....

Name: (please print): Helen Dodd

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Project Playtime

KEY TRIAL CONTACTS

Chief Investigator	Professor Helen Dodd, 0771155600, h.dodd@exeter.ac.uk
Trial Co-ordinator	Bryony Longdon, b.longdon@exeter.ac.uk
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Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	UKRI – grant reference MR/S017909/1
Clinical Trials Unit	n/a
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Trials Pharmacist	n/a
Committees	n/a

i. LIST of CONTENTS

Project Playtime

ii. LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of Investigational Medicinal Product

Project Playtime

CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
DSUR	Development Safety Update Report
EC	European Commission
EMEA	European Medicines Agency
EU	European Union
EUCTD	European Clinical Trials Directive
EudraCT	European Clinical Trials Database
EudraVIGILANCE	European database for Pharmacovigilance
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
MA	Marketing Authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
MS	Member State
NHS R&D	National Health Service Research & Development
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
RCT	Randomised Control Trial

Project Playtime

REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOP	Standard Operating Procedure
SmPC	Summary of Product Characteristics
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

Project Playtime

iii. TRIAL SUMMARY

Trial Title	Evaluation of the Outdoor Play and Learning (OPAL) programme on the mental health of primary-aged children in England, a feasibility Randomised Controlled Trial	
Internal ref. no. (or short title)	Project Playtime	
Clinical Phase		
Trial Design	Feasibility RCT	
Trial Participants	Primary or Junior Schools	
Planned Sample Size	8 schools	
Treatment duration	18 months	
Follow up duration	1 month	
Planned Trial Period	36 months	
	Objectives	Outcome Measures
Primary	- to assess the feasibility and acceptability of study procedures such as process and outcome measures and the randomisation process, including continuing with usual practice if randomised to control arm - whether target recruitment and retention rates of schools, pupils and parents are feasible - appropriate health outcome and health economic measures for a subsequent definitive trial	The primary outcome measures are the progression criteria which use a traffic light system. Green criteria indicate support for progression to a full trial. Amber criteria indicate that a full trial may be possible but some changes may be required and/or consideration given. **Green criteria:** - No serious concerns have arisen about the acceptability of study procedures - At least 7/8 schools are successfully recruited, randomised and retained throughout the study

Project Playtime

	- the feasibility of collecting reliable data on children's play and physical activity - any changes needed to study procedures or outcome measures - whether there are any negative impacts of study procedures	- Participation rates at intervention and control schools retained in the trial are at least: 80% of teacher-reported SDQ at baseline. 80% retained at follow-up. 80% of child-report Stirling Wellbeing Questionnaire at baseline. 80% retained at follow-up. No marked differences in the characteristics of the children with missing data on teacher report measures when compared to those with complete data. Evidence that play has improved at intervention schools, based on at least two of the following: scan observations, focal observations, child-report and school-staff report, - There is evidence of at least adequate reliability for scan observations, focal observations and assessment of physical activity. - Measures used capture range of costs and benefits based on process evaluation and qualitative interviews. - No serious negative impacts have arisen.

Project Playtime

		Amber criteria: - At least 6/8 schools are successfully recruited, randomised and retained throughout the study - Participation rates at intervention and control schools retained in the trial are at least: 60% of teacher-reported SDQ at baseline. 80% retained at follow-up. 60% of child-report Stirling Wellbeing Questionnaire at baseline. 60% retained at follow-up. Any differences in the characteristics of the children with missing data on teacher report measures (when compared to those with complete data) are able to be handled successfully via statistical methods.
Secondary	n/a	n/a
Investigational Medicinal Product(s)	Outdoor Play and Learning (OPAL) play intervention for schools.	
Formulation, Dose, Route of Administration	18 month, mentor led programme, delivered in junior or primary schools.	

Project Playtime

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
UKRI	Financial support
University of Exeter	In kind support through covering staff time for health economics, trial management advice and statistics support.
Department of Health and Social Care	Excess treatment costs of paying for the OPAL programme all eight schools

v. ROLE OF TRIAL SPONSOR AND FUNDER

The funder has no role in the design or implementation of the trial; they fund the time for staff members and associated costs (e.g. travel to schools, dissemination costs etc.). The University of Exeter similarly has no role in the design or implementation of the trial but support staff time.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

There will be a Trial Advisory Group (TAG), which will include parents, teachers, academics and play professionals. The majority of members of the advisory board will be independent of the University of Exeter, UKRI and OPAL. The TAG will meet regularly to ensure all practical details of the trial are progressing well and working well and everyone within the trial understands them. Any issues that arise during the trial will be discussed with the TAG.

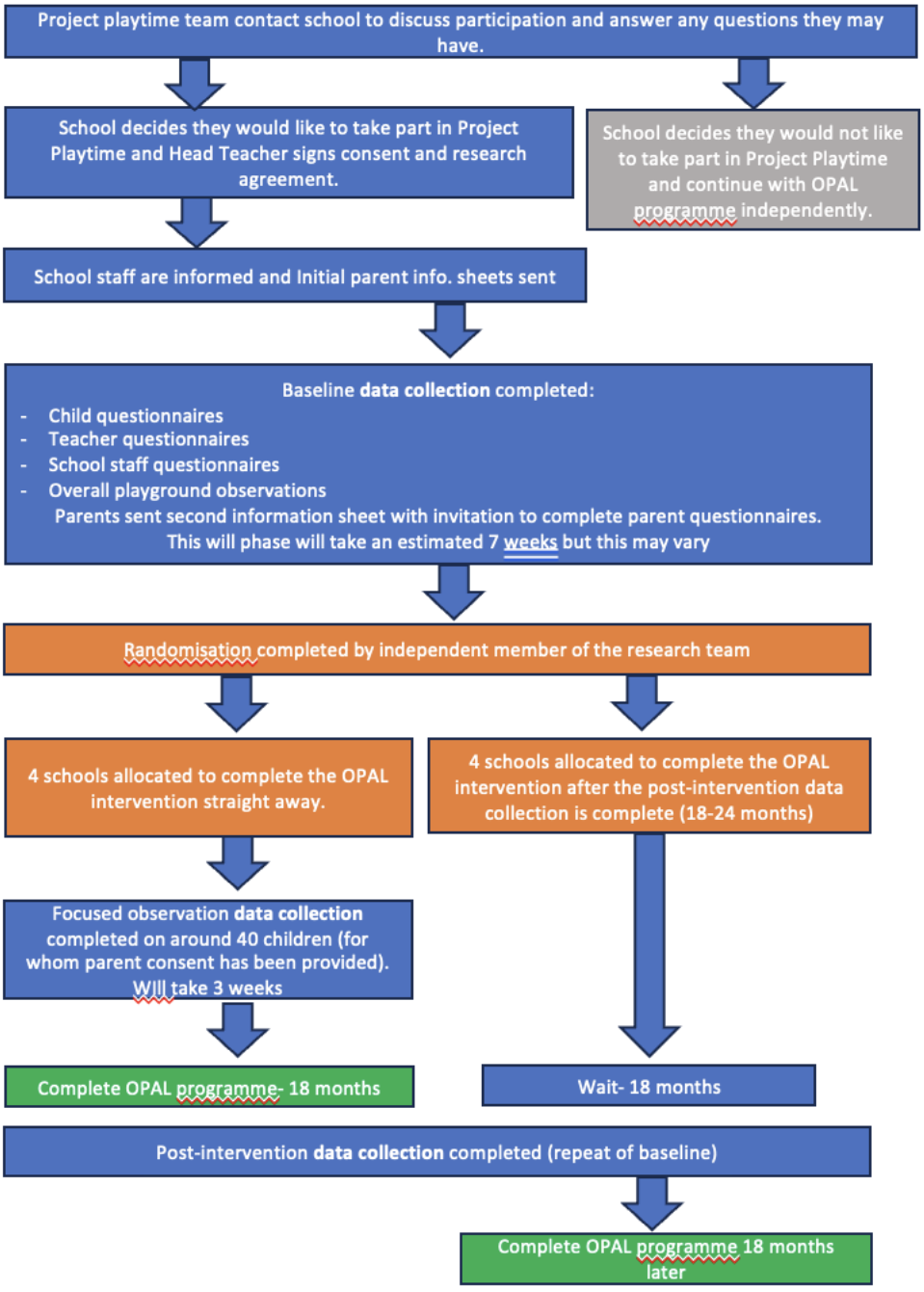
vii. Protocol contributors

The protocol has been written by Helen Dodd, with support from Bryony Longdon. The protocol was developed with input from experts in statistics (Prof. Obi Ukoummune), health economics (Prof. Claire Hulme) and trial design (Prof. Katrina Wyatt). The proposal has been influenced heavily by initial pilot work conducted at two primary schools by the above research team and colleagues Dr Lily FitzGibbon and Dr Rachel Nesbit as well as student researchers who collected data in schools. Head teachers, school staff, parents and children have been involved in the development of the protocol, primarily through close working during the pilot stage and one to one interviews at the end of the research and intervention.

viii. KEY WORDS: School-based intervention, playtime intervention, play, mental health, recess, breaktimes

Project Playtime

ix. TRIAL FLOW CHART



Project Playtime

1 BACKGROUND

Mental health problems are a leading cause of disease burden (1). The economic costs of mental ill health in England are estimated at £105.2bn per year. Pathways to mental health problems begin in childhood with emotional disorders such as anxiety having a particularly early onset (2). Emotional disorders are also the most common mental health disorders; affecting more than 250,000 primary school-aged children in England (3). To reduce mental ill health, prevention during childhood is key (4). Time outdoors is linked to improved wellbeing in children, which protects against poor mental health (5). Outdoor time provides children with a unique opportunity for boisterous, adventurous, active, child-led, play and there is increasing evidence that this type of play has positive effects on children's mental health (6). Despite this, opportunities for outdoor play are declining in and outside of schools. Given this, the proposed research will inform the feasibility of conducting a full Randomised Controlled Trial (RCT) of a school-based intervention to improve the quality of outdoor play in English primary/junior schools, as a route to reducing mental health problems and improving wellbeing and enjoyment of school.

Initial evidence supports school programmes that aim to improve outdoor play as beneficial for children's mental health and well-being. For example, Lavrysen et al. (5) gave school children opportunity to engage in child-led play, including exploring risks. Post-intervention, significant improvements were found in teacher ratings of children's self-esteem, conflict sensitivity and concentration. Other school programmes have introduced recycled materials for children to play with and found improvements in physical activity and cognitive development, but mental health has not been assessed.

In this research we will work with Outdoor Play and Learning (OPAL) who have created an intervention that aims to make playtimes better for children. The programme helps schools to provide excellent play for all children every day. It has been developed over 20 years with input from teachers, parents and children. Many primary schools have already done the programme and preliminary evaluations of OPAL have been positive, reporting increases in resilience and improvements in children's happiness and wellbeing (14, 15). There has not yet been a strong scientific assessment of how the OPAL programme affects children's mental health and wellbeing. Furthermore, the mental health outcomes of school-based outdoor play programmes have yet to be examined systematically. There is convincing evidence though from other contexts, such as hospitals, that child-led play can improve children's mental health and wellbeing (16, 17).

The OPAL programme provides participating schools with an experienced mentor who supports the school over the course of an 18-month period to change their playtimes (see later intervention section for more details). and setting goals for the programme, later sessions include a training session for staff where they learn about theory and practice in playwork. Playworkers are trained to create environments to ensure play opportunities are as diverse and inclusive as possible, to observe, reflect and analyse the play that is happening and to make changes to the environment if needed. The guiding principle underlying this approach is that where possible play should be freely chosen, child

led and intrinsically motivated. Often adults make choices about what children should play and set constraints and rules around children's play (e.g. 'lets play hide and seek, you hide I'll count). Playwork training helps adults working with children to understand that their role is to create a playful environment and then to step back and allow children to lead the play. When children direct their own play, in a diverse environment they will naturally challenge themselves in their play in a way that is stretching but appropriate for them. The play programmes therefore increase adventurous play by working to provide children with more space and permission to lead their own play.

In addition, schools would be encouraged to introduce loose parts for play such as tyres and milk crates which give children more opportunity for creative, child-led play which may be adventurous in nature. Further sessions provided as part of the programme include what is called risk-reframing training for teachers and parents. During these sessions teachers and parents are taught how to implement the risk benefit approach recommended by the Health and Safety Executive (see https://www.hse.gov.uk/entertainment/childs-play-statement.htm). This approach requires adults to consider risks in the contexts of benefits rather than taking a risk minimisation approach; often a risk also provides a learning opportunity (benefit) and therefore the risk may be justified because of the benefits it offers. For example, a balance beam has a risk that a child will fall off and hurt themselves but it has the benefit of giving children an opportunity to practice balancing and to develop their balance skills. The final sessions focus on including play within school policies and documentation and ending the mentoring with future planning and goal-setting.

This current research will inform the feasibility of conducting a full Randomised Controlled Trial (RCT) of a school-based intervention to improve the quality of outdoor play in English primary/junior schools, as a route to reducing mental health problems and improving wellbeing and enjoyment of school.

References

1. Children's Commissioner. The state of children's mental health services 2019/2020 [Available from: https://www.childrenscommissioner.gov.uk/wp-content/uploads/2021/01/occ-the-state-of-childrens-mental-health-services-2019-20.pdf.
2. Ford, T., et al. (2003). The British child and adolescent mental health survey 1999: The prevalence of DSM-IV disorders. Journal of the American Academy of Child & Adolescent Psychiatry, 42(10), 1203-1211.
3. Kessler, R.C., et al. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Archives of General Psychiatry, 62, 593-602.
4. Hudson, J. L., & Dodd, H. F. (2012). Informing early intervention: Preschool predictors of anxiety disorders in middle childhood. PLoS One, 7(8), e42359.
5. Caspi, A., et al. (1988). Moving away from the world: Life-course patterns of shy children. Developmental Psychology, 24(6), 824-831. 6Essau, C.A., et al. (2002). Course and outcome of anxiety disorders in adolescents. Journal of Anxiety Disorders, 16(1), 67-81.
7. Sandseter, E. & Kennair, L. (2011). Children's risky play from an evolutionary perspective: The anti-

phobic effects of thrilling experiences. Evolutionary psychology, 9(2), 257-284.
8. Dodd, H.F., & Lester, K. (2021). Adventurous play as a mechanism for reducing risk for childhood anxiety: A conceptual model. Clinical Child and Family Psychology Review, 24, 164–181.
9. EnglandMarketing. (2009). Report to Natural England on Childhood and Nature. Retrieved from: publications.naturalengland.org.uk/file/5495287317528576.
10. Dodd, H.F., FitzGibbon, L., Watson, B.E., Nesbit, R.J. (2021). Children's Play and Independent Mobility in 2020: Results from the British Children's Play Survey. Int. J. Environ. Res. Public Health, 18, 4334. https://doi.org/10.3390/ijerph18084334
11. Lester, S., Jones, O., & Russell, W. (2011). Evaluation of South Gloucestershire Council's Outdoor Play and Learning (OPAL) Programme. http://outdoorplayandlearning.org.uk/wp-content/uploads/2016/07/supporting-school-improvement-through-play-1.pdf

2 RATIONALE

In England, 1 in 6 children have a probable mental health disorder and over half a million children are referred to NHS mental health services per year (7). Government strategy and policy highlight that child mental health is an important, long-term issue (8) and that better prevention is required (9). Emotional problems such as anxiety are the most common disorders experienced in childhood and they predict long term mental health problems (10). They are therefore a crucial target for prevention.

There is substantial health inequality apparent in children's mental health problems; there is an overrepresentation of girls, children with special educational needs and children from low income families (3). As state primary schools have near universal coverage of children, prevention programmes delivered in schools have the potential to address these health inequalities as well as the sequalae of inequalities that occur as a result of having a mental health problem.

Prevention of anxiety and emotional problems more broadly typically involves CBT-based approaches, either targeted or universal, which teach children (or their parents) the principles of CBT. These approaches have had mixed success.

Recent theory proposes that adequate freedom to play may provide an opportunity for children to learn some of what would be targeted in a CBT-based prevention programme, such as adaptive coping styles, unbiased appraisal of physiological arousal and prevention of avoidance (Dodd & Lester, 2021). In support of this theory, initial research shows that children who spend more time playing outdoors and more time playing adventurously have fewer emotional problems (11). Despite this, children spend less time playing outdoors now than in previous generations (12) and the proportion of children playing with friends after school has also significantly declined (13). These changes mean that school playtime is an increasingly important opportunity for children to play outdoors. Since 1995 though, playtimes have decreased by 45 minutes per week and most schools focus on risk minimisation and containment during playtime (13).

Project Playtime

This feasibility RCT focuses on reducing children's mental health problems via a programme designed to improve child-led outdoor play in schools. The Outdoor Play and Learning (OPAL) programme aims to harness playtimes to provide every child with access to rich outdoor play opportunities, as a route to decreasing inequality in access to outdoor play and, in doing so, reducing children's risk for mental health problems and increasing their wellbeing and enjoyment of school. The OPAL programme is established and has been implemented at many schools but only initial evaluations have been conducted, none of which would be considered a clinical evaluation (14).

The intervention will be delivered at school-level (with schools as study participants) and is therefore a universal intervention. The intervention delivery time, based on careful development by OPAL, is 18 months. Control schools will be asked to continue with usual practice at playtimes during this period, as this is considered least disruptive. Control schools will be given the intervention after the 18 month wait period. No children will be prevented from seeking support for their mental health during this period, as this falls within usual practice.

The aim of the research is to determine the feasibility of progressing to a cluster RCT of an outdoor play programme for primary/junior schools which aims to improve the quality of children's outdoor play as a route to decreasing children's risk for mental health problems and improving children's wellbeing and enjoyment of school.

2.1 Assessment and management of risk

Schools will be recruited after they have decided to complete the OPAL programme; they will not be asked to complete the programme as part of the research. This means that the risks of the research are low. There is a cost in terms of lesson time but we have evaluated this together with teachers and school leaders who advise that the disruption is minimal and the importance of the research justifies this time.

The OPAL programme involves training in risk benefit assessment and supports schools to provide opportunities for children to explore risk-taking. This means that there may be an increased in risky or adventurous play during playtimes (e.g. building dens, riding scooters, jumping onto and off tyres), and there may be an associated increase in injuries. The OPAL programme has been implemented in hundreds of schools and, anecdotally, schools report that injuries *decrease* when the programme is implemented. We therefore consider this to be a low probability risk. Furthermore, with the training that OPAL provide, school staff will be well prepared for identifying and stopping play that is considered dangerous.

This trial is categorised as:

- Type A = No higher than the risk of standard medical care

Project Playtime

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

The aim of this project is to determine the feasibility of progressing to a cluster RCT (with intervention and waitlist arms) of an outdoor play programme for primary/junior schools which aims to improve the quality of children's outdoor play as a route to decreasing children's risk for mental health problems and improving children's wellbeing and enjoyment of school.

No hypotheses are evaluated because this is a feasibility trial.

3.2 Secondary objectives

n/a

3.3 Outcome measures/endpoints

See table below.

3.4 Primary endpoint/outcome

The primary outcome for the full RCT will be teacher-reported scores on the Emotional Difficulties scale of the SDQ.

For the feasibility RCT, the primary outcome will be the progression criteria. The progression criteria use a traffic light system. Green criteria indicate support for progression to a full trial. Amber criteria indicate that a full trial may be possible but some changes may be required and/or consideration given. If neither Green nor Amber criteria are met there may be significant concerns about progressing to a full RCT.

Green criteria:

- No serious concerns have arisen about the acceptability of study procedures
- At least 7/8 schools are successfully recruited, randomised and retained throughout the study
- Participation rates at intervention and control schools retained in the trial are at least:
    - 80% of teacher-reported SDQ at baseline. 80% retained at follow-up.
    - 80% of child-report Stirling Wellbeing Questionnaire at baseline. 80% retained at follow-up.
- No marked differences in the characteristics of the children with missing data on teacher report measures when compared to those with complete data.
- Evidence that play has improved at intervention schools, based on at least two of the following: scan observations, focal observations, child-report and school-staff report,
- There is evidence of at least good reliability for scan observations, focal observations and assessment of physical activity.
- Measures used capture range of costs and benefits based on process evaluation and qualitative interviews.

- No serious negative impacts have arisen.

Amber criteria (where no amber criteria exist, the green criteria apply):

- At least 6/8 schools are successfully recruited, randomised and retained throughout the study

- Participation rates at intervention and control schools retained in the trial are at least:

    - 60% of teacher-reported SDQ at baseline. 80% retained at follow-up.

    - 60% of child-report Stirling Wellbeing Questionnaire at baseline. 60% retained at follow-up.

- Any differences in the characteristics of the children with missing data on teacher report measures (when compared to those with complete data) are able to be handled successfully via statistical methods.

- There is evidence of at least adequate reliability for scan observations, focal observations and assessment of physical activity.

3.5 Secondary endpoints/outcomes

N/A

3.6 Exploratory endpoints/outcomes

N/A

3.7 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective To determine the feasibility of progressing to a cluster RCT (with intervention and waitlist arms) of an outdoor play programme for primary/junior schools which aims to improve the quality of children's outdoor play as a route to decreasing children's risk for mental health problems and improving children's wellbeing and enjoyment of school.	Outcomes are the progression criteria (see above)	Monitored throughout the study

Secondary Objectives Example: To assess the safety of treatment A in <insert condition/population>	N/A	
Tertiary Objectives Please add if applicable, otherwise delete this row	N/A	

4 TRIAL DESIGN

The study is a feasibility RCT using a cross-over design (but note that outcomes are not assessed post-intervention in the waitlist group due to time constraints) with usual practice as the control condition. The full RCT would be designed to test the superiority of the intervention when compared to usual practice.

5 TRIAL SETTING

The trial will be run through eight participating schools. Participating schools will be referred to the trial through OPAL once they have approached them and agreed to do the programme.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 Inclusion criteria

Schools must be at least single form entry (~30 children per year or more). Schools will initially be recruited through pre-specified regions covering the SW of England (Cornwall, Devon, Bristol, Bath, Dorset and Wiltshire). If necessary this area may be expanded.

6.2 Exclusion criteria

Schools who primarily support children with Special Educational Needs or Developmental Disorders will not be included because the intervention is designed for mainstream schools at this stage.

Although recruitment focuses on the school level, note that data will not be collected about children in years 5 and 6 because they will have left the schools by the post-intervention phase.

7 TRIAL PROCEDURES

From January 2024 to July 2024 schools who contact OPAL and agree to complete the programme will be assessed for eligibility to participate in the study until eight schools have been recruited.

Eligible schools will be given information by OPAL about the research and asked to consent to OPAL providing the research team with their contact details. If they consent, the relevant OPAL mentor for the region will provide the research team with these contact details.

The research team will then contact the school to discuss participation, providing detailed information sheets, which will have been assessed and approved by the University of Exeter ethics committee.

The research team will answer any questions the school may have and then ask the head teacher to provide consent for the school to participate in the research.

If consent is given, baseline data collection will be scheduled. The baseline data collection period takes an estimated 7 weeks. This will be scheduled for the next available slot.

Once baseline data collection is complete, schools will be randomised to either the intervention or control condition. Randomisation will be done in pairs of schools to allow the intervention to begin as soon as possible, rather than waiting for baseline measures to be complete at all 8 schools.

Focal observations of play will be conducted at all schools allocated to the intervention arm. When these are complete, the research team will inform the OPAL mentor that they can begin the programme.

After 18 months, data collection will be completed at all intervention and control schools who remain in the trial.

Control schools will then complete the intervention.

Interviews will be conducted at baseline, 9 months and 12 months as a process evaluation.

Qualitative interviews will be conducted at the end of the intervention (at intervention schools) to evaluate experiences and outcomes of the intervention.

7.1 Recruitment

From January 2024 to July 2024 schools who contact OPAL and agree to complete the programme will be assessed for eligibility to participate in the study until 8 schools have been recruited.

Eligible schools will be given information by OPAL about the research and asked to consent to OPAL providing the research team with their contact details. If they consent, the relevant OPAL mentor for the region will provide the research team with these contact details.

The research team will then contact the school to discuss participation, providing detailed information sheets, which will have been assessed and approved by the University of Exeter ethics committee.

The research team will answer any questions the school may have and then ask the head teacher to provide consent for the school to participate in the research.

The OPAL mentors will be asked to keep a record of the number of schools who were ineligible as well as those who were eligible but declined to be contacted about the research; characteristics of these schools and reasons will be recorded where possible.

The research team will keep records of the number of schools who consented to be contacted but did not consent to participate in the research. Characteristics of these schools and reasons will be recorded where possible.

7.1.1 Participant identification

Project Playtime

The three OPAL mentors covering the South-West regions will identify participants (schools). The research team will provide them with our eligibility criteria and information sheets about the research. When a new school signs an agreement with them to complete the OPAL intervention, the mentor will assess the school for eligibility as a research participant. If they are eligible, they will give them the information sheets and seek consent for the research team to contact the school about participation.

7.1.2 Screening

None

7.1.3 Payment

We will pay for all eight schools to receive the OPAL programme. We will pay OPAL directly. Alongside the intervention, schools will receive financial support of £2500 to cover the cost of staff time to support the research. £1250 will be paid to each school after completion of baseline data, and £1250 will be paid to each school after completion of follow up data.

In addition, parents and schools staff will receive £5 vouchers in return for their time completing questionnaires. School staff who take part in process evaluation interview or the qualitative research will be given a £20 voucher in return for their time.

7.2 Consent

Headteachers will be given detailed study information sheets and will provide informed consent for the school to participate in the research. The OPAL intervention falls within usual curriculum and other institutional activities (BPS, code of human ethics 2010, p.17) so no additional consent from parents is required for the intervention to be ran at the school. The headteacher will provide informed consent for all children in their care in Years 3 and 4 at baseline to complete questionnaires and for teachers of children in Year R to Year 4 to complete a questionnaire for all children in their class. They will also give consent for playtimes to be observed, but only in a way that does not lead to individual-level data (e.g. how many children are climbing?).

Parents will have a right to refuse their child's participation and children will have the right to refuse to participate. In both cases, no reason needs to be given and there will be no adverse consequences.

Children will be told about the research generally in a school assembly led by the research team, once before the baseline data collection, and again before the post-test data collection. During this assembly we will give children the opportunity to ask questions and explain what they should do if they don't want to take part or if they have any questions later on. In both cases they should speak to their teacher who can let us know. Prior to completing the measures in class, children will be shown a short animation explaining what they are being asked to do and why. This will explain that they can choose not to answer the questions if they don't want to and that they can ask their teacher if they have any questions. Researchers will then answer any questions the children may have before they hand out the questionnaires.

Parents will be given information about the trial which will include contact details. The process for withdrawing data and consent will be explained in this information sheet.

Parents will give active consent for completing questionnaires about their child, for their child to be observed playing (in a way that leads to information about an individual child's play) and for their child to participate in a qualitative interview. Parent will be able to consent to any, all, or none of these, as they wish; there will be no pressure to consent.

School staff will give active consent for completing questionnaires about playtime and for participating in qualitative interviews.

7.2.1 Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

n/a

7.3 The randomisation scheme

Method of randomisation is simple randomisation with a 1:1 allocation ratio. Schools will be randomised one pair at a time.

7.3.1 Method of implementing the randomisation/allocation sequence

Schools will be randomised to the intervention (OPAL) or usual school practice arm in a 1:1 ratio using blocked randomisation of 4 blocks of two. An independent statistician will conduct randomisation via a computer-generated algorithm. Schools will be randomised after school enrolment and baseline assessments have been completed. The independent statistician will pass the allocation to the research team who will inform schools and parents/carers which arm they are allocated to.

7.4 Blinding

It is not possible for participants to be blind or to guarantee that observers will be blind because the changes made to playtime will likely be obvious. To minimise bias, the post-test observers will not be explicitly told which condition each school is in whilst conducting the main evaluation (they will be unblinded for the focal observations as these are only conducted at the intervention schools). Study statisticians will remain blind to school/participant trial arm at least until completion of the primary analyses. Health economists will need to be unblinded in order to conduct economic analyses.

7.5 Emergency Unblinding

N/A

7.6 Baseline data

Project Playtime

Baseline data includes:

- Parent-report questionnaires
- Teacher-report questionnaires
- Child-report questionnaires
- Observations of play

Other measures and information are sought via interviews for a qualitative evaluation of the intervention and process evaluation of the intervention implementation and research.

Each are outlined in the table below under relevant headings. Note that most measures are included because they would be used in a full RCT to examine the primary or secondary outcomes, or to examine whether the programme successfully changes play (the proposed mechanism through which the programme would affect mental health). We have explained the relevance of each measure to a full RCT. Because this is a feasibility trial, the research questions focus on the feasibility of using these measures within a full RCT.

Method	**Relevance within a full trial**
Parent report measures ***(Parents/carers of children in Years R-4 (at baseline)***	
Parent/carer reported demographic information about child and parent/carer	The data will be used to describe the sample and to ensure sufficient diversity in the focal observation subsample (see below), where we want to ensure diversity in child sex, age, ethnicity and wellbeing.
Strengths and Difficulties Questionnaire (SDQ) with impact section	Child internalising problems, as measured via the SDQ internalising subscale would be compared from baseline to post-test.
Ofsted Parent View Questions	We will use the Ofsted questionnaire to give us insight into whether the play programme has affected children's enjoyment of school and parent's perceptions of the school in a broad sense.
Child Health Utility Instrument (CHU9D)	The CHU9D will be used in a full RCT for health economics evaluation by providing Quality Adjusted Life Years (QALYS).
Tools_for_schools-resource-use-questionnaire (parent report)	The resource use questionnaire will be used in a full RCT for health economics evaluation, comparing service use between those who attend the intervention school and those who attend control schools.
Teacher report measures	

Project Playtime

(children YR to Y4 at baseline)	
SDQ with impact section	Child internalising problems, as measured via the SDQ internalising subscale would be compared from baseline to post-test (likely primary outcome measure for full RCT).
Child self-report measures	
Activities During Playtime questionnaire	This measure allows children to tell us about what they play and will provide insight into how play has changed in terms of activities. It contributes to analysis of the extent to which the programme changes play (the proposed action through which is may affect mental health).
Emotions during playtime	The measure will be completed on two occasions at baseline and two occasions at post- intervention. Scores for negative affect and positive affect will be averaged together to give one baseline score per child and one post-test score per child. Scores on specific items related to adventurous play (excited, scared, fearless, daring) will also be averaged across the two completions to allow examination of changes in these emotions over time. Finally, the item 'lonely' will be averaged across the two completions and examined as a potential factor that may change as a result of the intervention.
How I feel about my school questionnaire	Items will be summed to give an overall score for positive feelings about school. This will be used to evaluate change from baseline to post-intervention.
Autonomy in Play and Challenge in Play Scales	Items will be summed to give an overall score for each scale. This will be used to contribute to an evaluation of change in play from baseline to post-intervention.
Social interaction during breaktime (1 question)	In a larger scale RCT we may include changes in social interaction within statistical models to control for the influence that this may have no wellbeing.
Stirling Children's Wellbeing scale	It is planned that the wellbeing scale will serve as a secondary outcome in a full RCT.
School staff report **(all school staff involved in the planning and supervision of playtimes)**	
Supervisor Risk Engagement and Protection Survey [S-REPS]	One of the targets of the programme will be supervisors' attitudes to risk. In particular, supervisors will be encouraged to consider

Project Playtime

	allowing children to assess their risk more independently, and to consider the risk-benefit profile of a behaviour rather than to simply seeking to reduce all risk. We will thus compare self-reported attitudes before and after the programme.
Supervisor report of breaktime activity (bespoke questionnaire)	Responses will contribute to the assessment of whether play has changed as a result of the intervention.
Supervisor report of barriers to implementing play interventions.	We are interested to see whether the OPAL programme is able to address all of these barriers and whether addressing them is linked to changes in children's play.
Observations of play	
Multidimensional Toolkit for the Assessment of Play in Schools (M-TAPS) Scan observations.	During the M-TAPS scan observations, the entire playground is scanned and observers count each: 1) activity type; 2) probability of adventure; 3) affect; 4) physical activity level. Activity count data will feed into evaluation of changes in play between pre and post-intervention.
Intervention schools only: Multidimensional Toolkit for the Assessment of Play in Schools (M-TAPS) Focal observations.	A subsample of 40 children from each intervention school (160 total) from Years 1-4 (at baseline) will be observed in focal observations. 20 of these children will have at least 'slightly elevated' (a score of 4 or higher) scores on the SDQ emotional difficulties scale based on parent measures at baseline; 20 will be age and gender matched controls whose scores on the SDQ emotional problems subscale are within the 'Close to average' range. Focal playground observations capture activity type, probability of adventure, affect and activity level of each child in the focal subsample. All children will be observed twice and then averaged together across days. Reliability assessments will be conducted on approximately 20% of the observations. Intra-class correlation will be used to evaluate reliability of coding. The data collected will be used to contribute to the evaluation of how play has changes from baseline to post-intervention (including an evaluation of whether changes are seen for both groups of selected children).

Project Playtime

Additional measures and information	
Qualitative interviews with children about their experiences of the playtimes (post-intervention only).	Qualitative interviews will be conducted to determine the pros and cons of the play programme from children's perspectives. These will be crucial for determining whether the programme had any unexpected effects on children that were not captured by other measures. It will also provide a more in-depth understanding of the programme from the child's perspective.
Qualitative interviews with school staff about their experiences of the OPAL intervention (post-intervention only.	Qualitative interviews will be conducted to determine the pros and cons of the adventurous play programme. These will be crucial for determining whether the programme had any unexpected adverse or positive effects on children and school staff that were not captured by other measures. These will also be used to identify any perceived barriers to implementing the programme that can be resolved prior to a full trial.
Process evaluation interviews	The OPAL mentor delivering the programme, headteacher and the school lead(s) for implementation at the intervention schools will be interviewed at baseline, 9- and 18-months. Headteachers from the control schools (and any other staff who have been involved heavily in the research) will be interviewed at 18 months only. Qualitative interviews will be conducted to capture how they believe the programme will 'work' in that school, any issues that arise during implementation and whether and how the changes will be sustained.

7.7 Trial assessments

Assessments will be conducted at each school at baseline (estimated January – July 2024) and at post-intervention (estimated November 2025 – May 2026). The post-intervention assessment will be completed approximately 18 months after the OPAL programme begins. Given that the programme takes 18 months to complete, this is an immediate post-intervention assessment point.

The same measures will be completed at each assessment, as detailed above, with the exception of the qualitative and process evaluation interviews (as detailed above) and the Tools for Schools resource use measure, which will only be completed by parents at post-intervention.

7.8 Long term follow-up assessments

There is no long term follow-up planned due to funding restrictions.

7.9 Qualitative assessments

One to one qualitative interviews will be conducted with children and school staff, as detailed in the table above. Interviews will be transcribed and analysed using inductive thematic analysis. A process evaluation will also be included, which will include interviews will key school staff regarding the intervention and the research (see table above).

7.10 Withdrawal criteria

Given the focus of the intervention, we do not anticipate that it would be necessary to withdraw a school from the trial (nor an individual child) for medical reasons.

Given that this is a feasibility trial, any situation where a school withdrew would be documented and, where possible, a process evaluation interview would be conducted to gain a better understanding of the decision to withdraw.

7.11 Storage and analysis of clinical samples

n/a

7.12 End of trial

n/a

8 Intervention

The OPAL programme will provide participating schools with an experienced mentor who supports the school over the course of an 18-month period to change their playtimes. The schools have autonomy over decision-making and they implement all aspects of the programme themselves in ways that work for them. The mentors are there to provide advice and guidance, not to deliver any of the implementation. The programme includes six planned sessions with the school which each has a specific focus. The first, for example, focuses on auditing the current play provision at the school and setting goals for the programme, later sessions include a training session for staff where they learn about theory and practice in playwork. Playworkers are trained to create environments to ensure play opportunities are as diverse and inclusive as possible, to observe, reflect and analyse the play that is happening and to make changes to the environment if needed. The guiding principle underlying this approach is that where possible play should be freely chosen, child led and intrinsically motivated. Often adults make choices about what children should play and set constraints and rules around children's play (e.g. 'lets play hide and seek, you hide I'll count'). Playwork training helps adults working with children to understand that their role is to create a playful environment and then to step back and allow children to lead the play. When children direct their own play, in a diverse environment they will naturally challenge themselves in their play in a way that is stretching but appropriate for them. The play programmes therefore increase adventurous play by working to provide children with more space and permission to lead their own play. In addition, schools would be encouraged to

introduce loose parts for play such as tyres and milk crates which give children more opportunity for creative, child-led play which may be adventurous in nature. Further sessions provided as part of the programme include what is called risk-reframing training for teachers and parents. During these sessions teachers and parents are taught how to implement the risk benefit approach recommended by the Health and Safety Executive (see https://www.hse.gov.uk/entertainment/childs-play-statement.htm). This approach requires adults to consider risks in the contexts of benefits rather than taking a risk minimisation approach; often a risk also provides a learning opportunity (benefit) and therefore the risk may be justified because of the benefits it offers. For example, a balance beam has a risk that a child will fall off and hurt themselves, but it has the benefit of giving children an opportunity to practice balancing and to develop their balance skills. The final sessions focus on including play within school policies and documentation and ending the mentoring with future planning and goal-setting. Initial evidence shows that when programmes of this nature are implemented, children become more physically active, take more risks in their play, and become more social and creative [13]. We have just completed a pilot study working with two schools who implemented the OPAL intervention. In the pilot study we conducted baseline and post-test data with two schools, who both successfully completed the OPAL programme and reported positive outcomes; the process of working with these pilot schools has informed the design of this study. As a result of the pilot work we have tested most of the procedures that we will use in this study and made some adaptations based on our learning and the feedback from the schools (e.g. increasing the window for the intervention to 18 months).

10 STATISTICS AND DATA ANALYSIS

The primary objective is to examine feasibility. The analysis will therefore focus on the following:

- Whether any serious concerns or serious negative impacts have arisen about the acceptability of study procedures or impacts of the intervention. This will be based on informal communication with the schools, formal communication with the schools, as well as the process interviews and qualitative interviews.

- The number of schools who were successfully recruited, randomised and retained throughout the study (including a record of those who were approached but declined or withdrew).

- Participation rates at intervention and control schools for the following measures:

    1. teacher-reported SDQ at baseline and post-intervention.

    2. child-report Stirling Wellbeing Questionnaire at baseline and follow-up for children in year 3 and 4 at baseline.

    3. Comparison using chi-square analysis of those with missing data vs. complete data on teacher report SDQ on demographic characteristics.

- Baseline to post-intervention comparisons of the following measures of children's play:

1. scan observations
2. focal observations
3. child-report
4. school-staff report,

- reliability analysis for:

1. scan observations
2. focal observations
3. observation of physical activity.

- Proportion of missing data on measures used capture range of costs and benefits.

In addition, inductive thematic analysis will be used to analyse the qualitative interviews, with a focus on whether the costs and benefits described are captured in the battery of questionnaires and observation.

Inductive thematic analysis will be used to conduct the process evaluation, once transcribing and coding are complete.

As this is a feasibility study, significance tests will not be performed. Intervention effects will be represented by point estimates and their standard deviations. Point estimates will be calculated by subtracting unadjusted mean data at post-intervention from the mean data at baseline. These will be used along with their standard deviations to inform sample size calculations for a definitive trial, if appropriate.

11 DATA MANAGEMENT

11.1 Data collection tools and source document identification

Data management plan as approved by funder, copied below.

0. Proposal name
Adventurous play as a route to decreasing children's risk for anxiety.
1. Description of the data
1.1 Type of study Data will be collected from human subjects within a feasibility randomised control trial of a school-based play intervention. **1.2 Types of data**

Project Playtime

Data will be quantitative, generated from questionnaires and live observations of children's play, and qualitative, generated from one-to-one interviews.

1.3 Format and scale of the data

All quantitative data will be stored as csv files and transcripts will be stored as rtf documents to ensure long term compatibility across software (see 3.1 for more detail).

The data generated is as follows.:

Feasibility study: pre and post data collected via parent and teacher questionnaires, where parents and teachers provide information about approx. 1200 children. Pre and post data from child questionnaires completed by an at least 480 children. Pre and post observation data from observations of an estimated 160 children. Pre and post questionnaire data from questionnaires for an estimated 160 school staff. All questionnaires completed online (via Qualtrics) and downloaded as csv files unless paper versions are preferred by schools. Where paper versions are collected, data will be entered into csv files and combined with downloaded data. Data quality will be checked by randomly sampling approx. 10% of data entered.

2. Data collection / generation

2.1 Methodologies for data collection / generation

Questionnaire data: questionnaires will be completed by parents, teachers, school staff and children. Online versions will be available with paper versions provided if requested. Qualtrics provides a secure online system for data collection.

Observation data: observations of children's play will be conducted using an established reliable coding scheme. Coding is completed live so no recordings are taken. An iPad app stores the data locally and then it is uploaded to the university SharePoint drives.

Qualitative data: qualitative data will be collected via one-to-one interviews using a topic guide that will be used flexibly and adapted, as recommended, throughout data collection.

2.2 Data quality and standards

Questionnaire data: online standardised questionnaires will be used where available. Where paper copies are used, they will be entered into Qualtrics and at least 10% will be checked by a second team member for accuracy. Surveys will be set-up to highlight any missed questions to participants. Data will be exported to CSV files.

Project Playtime

Observation data: Coders will be trained to be reliable (at least ICC = .8/Kappa = .8) by the PI prior to data collection. Coders live coding will be checked periodically to ensure reliability is maintained.

Qualitative data: Interviews will be conducted using a topic guide with detailed field notes kept.

Detailed records of the data collection processes will be made to support data sharing.

3. Data management, documentation and curation

3.1 Managing, storing and curating data.

All raw data files will be digital. Quantitative data will be stored as .csv files with corresponding explanatory files giving variable definitions. Interview data will be stored as MP4 files and then transcribed into an rtf file. Where necessary unique ID numbers will be used to link data across files. Where this is not required, data will be collected anonymously and no ID number will be required. Where ID numbers are required a separate file will contain identifying and, where required, contact details. This file will be password protected. Where paper consent forms are completed these will be stored securely in school or in a locked filing cabinet in the PI's office if they are not anonymised. Paper copies of questionnaires will be destroyed in confidential waste after the data has been entered. All files will be stored on the PIs allocated space on the University of Exeter's SharePoint. SharePoint is subject to regular backups and is secure and password protected. A curation document will be updated throughout the project to capture what data are stored in what file.

3.2 Metadata standards and data documentation

Procedures documents will be created to accompany the research data. Detailed explanations of how the data were collected, coded and entered will be provided. Furthermore, an index of variable names, variable labels and an accompanying explanation for each will be generated for each data file.

3.3 Data preservation strategy and standards

Anonymised data will be shared via the UK Data Service (note that data from the first stage of my FLF has already been shared here). Audio recordings of interviews will not be shared but anonymised transcripts will be shared with any identifying information retracted. Once interviews have been transcribed and quality checked, original recordings will be deleted.

Project Playtime

4. Data security and confidentiality of potentially disclosive information

4.1 Formal information/data security standards

Information held under the authority of the University of Exeter and managed in accordance with the University's Information Compliance policies. Data will be stored on the PI's allocated space on the University of Exeter's SharePoint. SharePoint is subject to regular backups and is secure and password protected. SharePoint allows files to be shared as necessary with other users (team members) without generated multiple copies and edit access can be restricted to protect the integrity of the data.

4.2 Main risks to data security

All the data collected for the study will be treated confidentially. The main risks are therefore that anonymised data could be linked back to individual responses by someone outside of the research team and/or that participants' personal contact details could be obtained by someone outside of the research team. The level of risk is moderate. To minimise this risk, the file that maps IDs to individual participants and the file containing participants contact details will only ever be saved on the secure University of Exeter SharePoint, in a folder that is separate to the study data, and these files will be password protected. Members of the project team will have access to these files on a need to know basis only. Raw questionnaire data will be saved initially on the secure Qualtrics servers, which meet data protection requirements and storage requirements. Identifying information and files that link individuals to data will be deleted as soon as they are no longer required and at the latest in July 2027, as indicated on the participant information sheets.

5. Data sharing and access

5.1 Suitability for sharing

All of the data collected from the research will be suitable for sharing with the exception of the interview recordings. The data can be shared because it can be anonymised entirely.

5.2 Discovery by potential users of the research/innovation data

Data will be shared via the UK Data Service along with a procedures document, curation document and description of variables. Links to the data record will be provided in all papers

published using the data. The data sharing policy will be explained to participants prior to their consenting to participate.

5.3 Governance of access

The anonymised data will be deposited with the UK Data Service and will therefore be made publicly and

freely accessible in the ReShare repository.

5.4 The study team's exclusive use of the data

Data will be made publicly accessible on publication of research findings or no later than 12 months after the completion of the grant, whichever is sooner.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Participants will be informed about plans for data sharing in the study information sheet and will consent to this when consenting to participate in the study. To ensure all data can be shared, only participants who consent to data sharing will be eligible to participate. Only anonymised data will be shared. Interviews will be recorded and transcribed. The recordings will not be made available as it may be possible for participants to be identified.

5.6 Regulation of responsibilities of users

Data will be made available under the terms of an open licence (such as Creative Commons Attribution) providing broad permission to re-use the data, subject to an attribution requirement.

6. Responsibilities

The PI has responsibility for data management within the project. Data held on University infrastructure will be managed in accordance with institutional information security policies.

Project Playtime

7. Relevant institutional, departmental or study policies on data sharing and data security	
Policy	**URL or Reference**
Data Management Policy and Procedures	https://ore.exeter.ac.uk/repository/handle/10871/26168
Data Security Policy	http://as.exeter.ac.uk/it/regulations/infosec/policy/
Data Sharing Policy	See 'Data Management Policy and Procedures'
Institutional Information Policy	See 'Data Security Policy'
Intellectual Property Policy	https://www.exeter.ac.uk/business/innovate/accesstoideas/
8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their **telephone & email contact details**	
Prof. Helen Dodd	

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Research Ethics Committee (REC) review& reports

Before the start of the trial, ethical approval was granted by the University of Exeter Medical School and Health and Care Professions Research Ethics Committee. Substantial amendments that require review by REC will not be implemented until the ethics committee grants a favourable opinion for the trial. All correspondence with the REC will be retained by the PI.

13.2 Peer review

The funder reviewed the application for funding to support the trial as detailed. An independent member of our faculty has peer reviewed our ethics application, which duplicates the information contained within this protocol. We have made adjustments to the ethics application and the protocol as a result of this feedback.

13.3 Public and Patient Involvement

The initial ideas for the research and the development of the application for funding were informed by PPI work which actively engaged a range of stakeholders, including children, parents, teachers and play experts. For the trial, we will recruit a Trial Advisory Group (TAG), which will include parents, teachers, academics and play professionals. The majority of members of the advisory board will be independent of the University of Exeter, UKRI and OPAL. The TAG will meet regularly to ensure all

practical details of the trial are progressing well and working well to share and discuss any challenges, issues, successes or unexpected events that arise during the trial.

13.4 Regulatory Compliance

The trial will not commence until it has been registered on the ISRCTN and favourable opinion has been given by the University of Exeter Faculty of Health and Life Sciences ethics committee.

13.5 Protocol compliance

The research team will follow the protocol and monitor compliance. Any deviations will be discussed with the TAG and where necessary documented and reported to the sponsor.

13.6 Notification of Serious Breaches to GCP and/or the protocol

The sponsor will be notified immediately of any case where a serious breach occurs during the trial conduct phase.

13.7 Data protection and patient confidentiality

See above data management plan.

All data will be collected, stored, handled and deleted in accordance with GDPR regulations.

13.8 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

The PI is a trustee of Play England but has no competing interests that are financial in nature.

13.9 Indemnity

The Chief Investigator and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a trial and they cannot offer any indemnity.

13.10 Amendments

Amendments to the trial protocol will be submitted to the University of Exeter Medical School and Health and Care Professions Research Ethics Committee for approval prior to being implemented. The sponsor will be informed of any substantial amendments that affect this protocol.

13.11 Post trial care

The OPAL intervention is designed to be implemented in such a way that the school are able to sustain it themselves once it is completed. The control group will complete the intervention after their wait period is complete. The intervention is not designed as a treatment so no participant will be left with a treatment need due to the end of the trial or the withdrawal of the OPAL intervention, should schools choose not to continue with the OPAL playtimes.

13.12 Access to the final trial dataset

Project Playtime

The research team led by the PI will have access to the final dataset until it is made available online via the UK data service, which is a requirement of funding. It will be submitted for sharing online before 31st July 2027.

14 DISSEMINIATION AND PUBLICATION POLICY

14.1 Dissemination policy

The primary output will be a written report on the feasibility of the OPAL play programme on the mental health of primary school children. Academic outputs will include academic papers and conference presentations. Alongside academic papers, the PI and her team also routinely provide non-academic summaries, including articles or blogs and webinars or podcasts. Here, we draw on our links with existing networks to support wider dissemination We will also provide audience-appropriate written summaries for the parents and carers involved in the study. No individual will ever be identifiable in any output.

14.2 Publication policy

All publications policy will be drafted before the study commences. It will state principles for publication, describe a process for developing outputs, contain a map of intended outputs and a timeline for delivery. The publication policy will respect the rights of all contributors to be adequately represented in outputs (e.g. authorship and acknowledgments) and the trial to be appropriately acknowledged. Authorship will be according to the individuals involved in the project.

15 REFERENCES

1. Children's Commissioner. The state of children's mental health services 2019/2020 [Available from: https://www.childrenscommissioner.gov.uk/wp-content/uploads/2021/01/occ-the-state-of-childrens-mental-health-services-2019-20.pdf.
2. Ford, T., et al. (2003). The British child and adolescent mental health survey 1999: The prevalence of DSM-IV disorders. Journal of the American Academy of Child & Adolescent Psychiatry, 42(10), 1203-1211.
3. Kessler, R.C., et al. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Archives of General Psychiatry, 62, 593-602.
4. Hudson, J. L., & Dodd, H. F. (2012). Informing early intervention: Preschool predictors of anxiety disorders in middle childhood. PLoS One, 7(8), e42359.
5. Caspi, A., et al. (1988). Moving away from the world: Life-course patterns of shy children. Developmental Psychology, 24(6), 824-831. 6Essau, C.A., et al. (2002). Course and outcome of anxiety disorders in adolescents. Journal of Anxiety Disorders, 16(1), 67-81.
7. Sandseter, E. & Kennair, L. (2011). Children's risky play from an evolutionary perspective: The anti-phobic effects of thrilling experiences. Evolutionary psychology, 9(2), 257-284.
8. Dodd, H.F., & Lester, K. (2021). Adventurous play as a mechanism for reducing risk for childhood anxiety: A conceptual model. Clinical Child and Family Psychology Review, 24, 164–181.

Project Playtime

9. EnglandMarketing. (2009). Report to Natural England on Childhood and Nature. Retrieved from: publications.naturalengland.org.uk/file/5495287317528576.
10. Dodd, H.F., FitzGibbon, L., Watson, B.E., Nesbit, R.J. (2021). Children's Play and Independent Mobility in 2020: Results from the British Children's Play Survey. Int. J. Environ. Res. Public Health, 18, 4334. https://doi.org/10.3390/ijerph18084334
11. Lester, S., Jones, O., & Russell, W. (2011). Evaluation of South Gloucestershire Council's Outdoor Play and Learning (OPAL) Programme. http://outdoorplayandlearning.org.uk/wp-content/uploads/2016/07/supporting-school-improvement-through-play-1.pdf

Project Playtime

16. APPENDICES

16.1 Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	V1.1	13/12/23	HD/BL	Updated progression criteria
2	V1.2	16/01/24	HD/BL	Update inclusion criteria to remove FSM

List details of all protocol amendments here whenever a new version of the protocol is produced.