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Project Playtime: Evaluation of the Outdoor Play and Learning (OPAL) programme on the wellbeing of primary-aged children in England

Submission date
04/01/2024

Recruitment status
No longer recruiting

Registration date
17/01/2024

Overall study status
Ongoing

Last Edited
12/09/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aims to conduct a feasibility study of the OPAL school-based play programme in primary schools, designed to increase children's opportunities for adventurous play as well as other play types. The aim is to determine the feasibility of progressing to a larger and more complex study of the play intervention. This more complex study would evaluate whether the programme might decrease children's mental health symptoms, increase their wellbeing and affect their enjoyment of school.

Who can participate?
Eight primary and junior schools in the South West of England will be taking part in the study.

What does the study involve?
Eight schools (who have already decided to complete the OPAL programme), will take part in the study. Four will be randomised to the intervention group and four will be in the control group. All schools will be asked to complete measures at the beginning and end of the study. The study will collect survey data from children, parents, teachers and school staff, observational data on children's playtime, and conducting qualitative interviews as part of the evaluation. Schools in the intervention group will start OPAL as soon as baseline data collection is complete. The control schools will receive OPAL after the end of the study.

What are the possible benefits and risks of participating?
Schools will have the OPAL programme paid for by the study. OPAL aims to improve the quality of children's outdoor play. This may decrease children's risk for mental health problems, improving children's wellbeing and improve children's enjoyment of school. 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.

Where is the study run from?
The University of Exeter (UK)

When is the study starting and how long is it expected to run for?
May 2022 to July 2027

Who is funding the study?
1. UKRI Future Leaders Fellowship
2. Medical Research Council
3. National Institute for Health and Care Research (NIHR)

Who is the main contact?
Professor Helen Dodd

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333480

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 58198, IRAS 333480

Study information

Scientific 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

Acronym
Project Playtime

Study objectives
No hypotheses are evaluated because this is a feasibility trial. This project aims to determine the feasibility of progressing to a full 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/12/2023, UEMS & Health & Care Professions Research Ethics Committee (University of Exeter, Stocker Rd, Exeter, EX4 4PY, United Kingdom; +44 (0)1872 256460; uemsethics@exeter.ac.uk), ref: 3647256

Study design
Randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental health

Interventions
Outdoor Play and Learning (OPAL) 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.

Eight schools (who have already decided to complete the OPAL programme), will take part in the study. Four will be randomised to the intervention group and four will be in the control group. Schools will be randomised to the intervention (OPAL) or usual school practice arm in a 1:1 ratio using blocked randomisation of four 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. 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 eight schools. All schools will be asked to complete measures at the beginning and end of the study. We will be collecting survey data from children, parents, teachers and school staff, observational data on children's playtime, and conducting qualitative interviews as part of the evaluation. Schools in the intervention group will start OPAL as soon as baseline data collection is complete. The control schools will receive OPAL after the end of the study.

As it is a feasibility study, progression criteria are used as the primary outcome. The measures include the teacher-reported Strengths and Difficulties Questionnaire (SDQ) a well-validated and reliable measure of children's mental health, which will be completed at baseline and follow-up. There will also be baseline and follow-up data from scan observations and focal observations to identify whether play has improved at intervention schools.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome measures are the progression criteria which use a traffic light system indicating support for progression to a full trial (Green), or that a full trial may be possible (Amber). These are measured using the teacher-reported Strengths and Difficulties Questionnaire (SDQ), child-reported Stirling Wellbeing Questionnaire, survey data, observational data and qualitative interviews at the beginning and end of the study.

Green criteria indicate support for progression to a full trial:
- 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 adequate reliability for scan observations, focal observations and assessment of physical activity.
- Measures used to capture a range of costs and benefits based on process evaluation and qualitative interviews.
- No serious negative impacts have arisen.

Amber criteria indicate that a full trial may be possible, but some changes may be required and /or consideration given:
- 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.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/07/2027

Eligibility

Key inclusion criteria
1. Schools must be at least single-form entry (~30 children per year or more)
2. Schools will 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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
8

Key exclusion criteria
1. Schools primarily supporting children with special educational needs or developmental disorders
2. Recruitment is at the school level, data will not be collected regarding children in years 5 and 6 because they will have left the schools by the post-intervention phase

Date of first enrolment
22/01/2024

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Exeter
St Luke's Campus
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Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. After the study has been completed (31st July 2027), all anonymised data will be archived and added to the UK Data Service ReShare repository (https://reshare.ukdataservice.ac.uk/). All participants will be asked for their permission for their anonymised data to be added to ReShare as part of the consent forms. Interview transcripts will not be shared publicly because participants may be identified by their responses.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version 1.2	11/11/2025	11/11/2025	No	Yes
Protocol file		16/01/2024	17/01/2024	No	No