STUDY SUMMARY

Scientific title:	The impact of interactive electronic devices: understanding the mechanisms of benefits and harms on young children's development, behaviour and health outcomes using a multimethod approach
Short title:	Impact of interactive electronic devices in the early years
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Version

Version	Date	Details of change
1	11th March 2024	Adapted the format of submitted application to NIHR protocol
2	25th March 2024	Added the Funder information

ABSTRACT

Primary research question

How do interactive electronic devices impact young children's development?

Background

Interactive electronic devices (IEDs), which we define as any portable screen such as tablets or mobile phones are ubiquitous in young children's lives, with 90% of children aged 3-4 years going online. National and international guidelines report lacking evidence of the impact of IEDs on health and development outcomes, limiting recommendations. Few studies have focused on IEDs, and those primarily use cross-sectional designs and show inconsistent results. In conversations with early years practitioners, parents and policymakers, they recognise IEDs as a valuable resource for early years learning. However, they also noted a negative impact on children's self-regulation, parent-child interaction and physical activity.

Aims

The project has the following interlinked aims, which will be addressed in three work packages (WPs):
WP1: To synthesise the evidence on the correlates of IED use in young children.
WP2: To study the long-term relationship between IED use (duration and mode) and emerging abilities (i.e., self-regulation, social development, executive function, language and numeracy) in 3 to 5 year old children.
WP3: To investigate the complexity in which young children use IEDs in their home environment.

Methods

WP1: We will systematically search the available evidence which reports the determinants or correlates of IEDs . If possible, we will synthesise the data using meta-analysis and categorise the correlates according to the levels of the socio-ecological model.
WP2: We aim to recruit 1,383 children. We will measure children's exposure to IEDs (i.e. time and content) and child emerging abilities (primary outcome). We will also include other secondary health, behaviour and educational outcomes (e.g., BMI, physical activity, motor skills, parent-child interaction and school readiness). We will use a multilevel regression model to examine the association between IED duration (hours per day) and mode (educational vs. non-educational; age-appropriate vs. non-age appropriate) with emerging abilities.
WP3: We will use videography to capture young children's IED use and interactions with family members. Interviews with parents and carers will complement the observations to further explore children's experiences and attitudes. We will use inductive thematic analysis to identify emerging themes.

Timelines for delivery

The project will commence in May 2024 and last for 48 months. WP1: completion of systematic review (1-12 months); WP2: design and recruitment, data collection, analysis, and reporting (3-41 months); WP3: Ethnographic study data collection, analysis and reporting (12-29 months); anticipated impact and dissemination (42-48 months).

Anticipated impact and dissemination

Discussions with the public and stakeholder engagement groups will inform the dissemination plan. The learning from this project will be disseminated through publications and will inform policy briefs distributed to health and educational organisations. We will also offer Knowledge Café events and information (newsletters, website) to early years settings. Combined, the studies proposed here will further elucidate the impact of IEDs on young children's health and development and identify any optimum level of IED use in terms of emerging abilities outcomes, informing population health guidelines and guiding future interventions.

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LIST OF ABBREVIATIONS

API	Application Programming Interface
BMI	Body mass index
CAFE	Comprehensive Assessment of Family Media Exposure Consortium
CINAHL	Cumulated Index to Nursing and Allied Health Literature
CRN	Clinical Research Network
CSBQ	Child Self-Regulation & Behaviour Questionnaire
DMC	Data Monitoring Committee
EA	Emerging Abilities
EPAO-SR	Environment and Policy Assessment and Observation Self-Report
ERIC	Education Resources Information Center
ESRC	Economic and Social Research Council's
EYFSP	Early Years' Foundation Stage Profile
EYP	Early years practitioner
EYT	Early Years Toolbox
GCSE	General Certificate of Secondary Education
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ICC	Intraclass Correlation Coefficient
IED	Interactive Electronic Devices
IMD	Index of Multiple Deprivation
MVPA	Moderate to Vigorous Intensity Physical Activity
NIH	National Institute of Health
NIHR	National Institute for Health Research
OHID	Office of Health Improvement and Disparities
PaRC	Practice and Research Collaborative within Yorkshire and Humber
PHIND	Public Health Intervention Development
PMG	Project Management Group

PPI	Patient and Public involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSDQ	Parenting Styles & Dimensions Questionnaire
PSG	Project Steering Group
SD	Standard Deviation
SEM	Socio ecological model
SPAI-SF	Smartphone Addiction Inventory - Short Form
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
SWiM	Synthesis Without Meta-Analysis
VPC	Variance Partition Coefficient
VRE	Video Reflexivity Ethnography
WP	Work Package

BACKGROUND

Interactive electronic devices (IEDs), defined here as tablets and smartphones, are ubiquitous in young children's lives. The UK Ofcom report "Children and Parents: media use, and attitudes" in 2022 (1) shows that 90% of children aged 3 to 4 years old go online. Of these, most children (78%) use tablets. The vast majority of children in this age range go online to watch YouTube (84%). However, only a minority of those watch it on dedicated YouTube apps for children (e.g., YouTube kids) (40%) (2, 3). The tactile□based digital interface of tablets and phones enables easy interactions that give young children greater independence but create challenges for parental supervision (4, 5). To date, few studies have focused on the impact of IEDs on health and health-related behaviour outcomes, and those primarily use cross-sectional designs (4-6) with inconsistent evidence on the benefits and harms. This study will address this gap in knowledge by undertaking an in-depth investigation of the available evidence (Work package (WP) 1), conducting a longitudinal study to explore the associations and optimal dose to minimise harms and maximise the benefits of IED use on emerging abilities (WP 2), and offering a qualitative insight into how children use IEDs in their home environment (WP 3). The logic model (Figure 1) illustrates the interactions between the project's components, our assumptions, and inputs, as well as how the activities will produce intermediate outcomes and long-term impact.

Despite a plethora of research on the effect of TV viewing on socio-emotional, cognitive and health outcomes in children (7-9), research on modern IEDs is scarce, with precise national and international policy guidance from paediatrics and physical activity guidelines still missing. For example, the UK Physical Activity Guidelines for Early Years reported a lack of evidence on the impact of "contemporary screen technology" on health and development outcomes (10). Likewise, the Royal College of Paediatrics and Child Health stated that evidence was too weak to recommend a 'safe' threshold for usage (11).

The dose-response relationship between IED and health and development outcomes are critical to informing population health guidelines and was identified as a gap in a systematic map of reviews that informed this funding opportunity (12). The review also highlighted the lack of longitudinal studies and understanding of the mechanisms of effect between screen use and mental wellbeing and psychosocial outcomes in children. This lack of clarity (and need for evidence-based guidance) has impacted parental decisions when guiding children on IED use, including parental uncertainty about the benefits or harms, particularly on children's development (13).

The scientific evidence in this field is conflicting and tends to focus on older children. Meta-analytic evidence indicated adverse effects of IEDs on sleep outcomes (inadequate sleep, poor sleep quality and excessive daytime sleepiness) in children and adolescents (6 to 19 years) (14). A cross-sectional study of younger children (<6 years) revealed that IED usage is associated with shorter sleep and sleep disturbances (15). Similarly, a systematic review linked smartphone overuse to visual impairment in children (>9 years) and young adults (16), while prolonged use (>5 hours per day) of tablets, smartphones, computers and video games combined was associated with obesity in adolescents (17).

Parents' excessive use of IEDs might also have a negative impact on children. A literature review reported

that parental use of mobile devices while around young children is associated with fewer and more negative parent-child interactions, with parents being less sensitive and responsive to their children's requests for attention (18).

Conversely, it has been argued that interactive technology can enhance learning and communication (19), by helping language learning in young children when content is co-viewed and discussed with parents (20). Similarly, a systematic review of the effect of tablets on learning and development found that most studies reported a positive impact on literacy development, mathematics, science, problem□solving, and self□efficacy in young children (2 to 5 years). However, the review consisted primarily of observational studies, which reported teachers' and parents' opinions and study quality was not reported (21). Finally, some experts suggest that interactive screen technology can reduce the gap in learning between those from more affluent and deprived areas (9). Learning apps might enhance social and language skills for children living in poverty and otherwise disadvantaged environments (9), showing potential to explore how these technologies could minimise the attainment gaps amongst children from diverse socioeconomic backgrounds. Although IED could reduce the educational gap, there is a concern about digital exclusion as 14% of households in the social grade D and E do not have internet access at home (22). Other experts believe using IEDs might not increase sedentary behaviour as much as other more passive screen viewings (e.g. TV) (9). They argue that some activity-based programs in these devices might encourage imitation or participation (23) or encourage children to explore the outdoors (24); however, there is still a lack of studies focusing on this relationship. Likewise, only a few studies have examined the association between IEDs and motor skills in young children, with contrasting results (4).

Nevertheless, the impact of IED on children's socio-emotional and cognitive development is undoubtedly the most relevant outcome for young children, as it is known that behavioural and psychosocial experiences in early life can affect brain development and behaviour (25). Multiple factors can influence development at a young age, including maternal education and linguistic competence (26), parental psychopathology and socioeconomic status (27). However, social environment and interactions also have a significant role (27) in young children's development, and IED’s influence on these factors might have a wider developmental impact.

There is contradictory evidence (28, 29) on the impact of IED on socio-emotional and self-regulatory skills, with researchers calling for more studies in this area (19). A recent narrative review reported that experimental research indicates that IED can be more beneficial for young children (0 to 5 years) learning and self-regulation compared to TV viewing. However, naturalistic studies showed that increased use of mobile devices is associated with poorer language and self-regulation (28). Likewise, a longitudinal study also found that young children (3 to 5 years) with higher levels of program viewing (TV or internet programs on any device) had increased externalising behaviour problems and total psychological difficulties 12 months later. Likewise, children who used apps for more than 30 minutes per day had lower inhibition (resisting distractions and impulsive behaviours) one year later. However, the study only included a small

sample of children (n=185), looked at multiple devices, including TV and video games and did not explore the screen media content (30).

The review that served as the basis for this NIHR call (12) also noted that few studies have looked at the experience of engaging in screen-based activities. A study which examined mothers' perspectives on preschoolers' use of screen activities, including mobile devices, reported that the devices are used for multiple purposes, including education and distraction. The study also reported contrasting views on the need to establish rules, and mothers also reported that mobile devices are an unavoidable part of life (31). Another study which looked at the context of use found that when parents need to do house chores, they allow children to use their mobiles to keep them calm, and some use the device to put their children to sleep (32). Nevertheless, we are unaware of any studies that have observed children in their home environment to learn about their behaviours and obtain insight into how they interact with IEDs and other family members.

Finally, very few studies have studied socioeconomic inequalities in IED use. This is important, as in the UK, by the age of 5 years, children from low-income families perform substantially below those from middle-income families in cognitive tests (33). This disadvantage may persist, later reducing academic achievement and employment and perpetuating inter-generational cycles of disadvantage (34), leading some to assert that the most effective and cost-effective way to prevent health inequalities is to intervene in early life (35). A systematic review and meta-analysis revealed that parenting stress, depression, unemployment, and low household income were risk factors associated with smartphone overdependence in mothers of preschoolers, which can negatively impact parenting capacity (36).

Formative work conducted by the applicants

In partnership with Kirklees Council, we conducted two qualitative studies exploring early years practitioners' (EYPs) and parents' perspectives on using IEDs. Studies were presented at international conferences, and the manuscripts are now in the final stages of preparation.

In the first qualitative study, we interviewed four early years practitioners (EYPs) from nurseries in low (n=2) and high (n=2) income areas in the Kirklees. The following main themes were identified: 1) The circumstances that contribute to increased use of IEDs with early years children; 2) The importance of acquiring knowledge and improved awareness of the benefits and harms of IEDs; 3) A balanced approach to new interventions requires a collaborative response; 4) Re-thinking the purpose of IEDs and how it integrates into children's lives.

In summary, the findings show that EYPs believe the circumstances relating to the increased use of IEDs with young children primarily relate to managing daily tasks, working commitments, busy parent schedules, generational changes, technological advances, parents' attitudes and habits surrounding IED use. The EYPs also revealed that IED can be used effectively and beneficially within an educational-based context, particularly with children with special educational needs. They highlight a need for acquiring more knowledge and awareness when considering the benefits and harms of IED use with

young children, with interventions aimed at teachers and parents. The EYPs stressed that adults must lead by offering positive modelling behaviour when using IEDs.

In the second qualitative study, we held two focus groups with parents from the nurseries in low (n= 5) and high (n=5) income areas. The thematic analysis revealed the following themes: 1) Differing opinions on how IEDs affect children; 2) Using IEDs for babysitting and entertainment when parents are busy; 3) Parent control and modelling around IEDs; 4) The need for gaining knowledge and interventions.

Findings revealed that although parents believe that IEDs are part of children's present and future, and therefore introducing them earlier might improve skill development (e.g., numeracy, literacy and fine motor skills), parents also believe that they can negatively affect children's sleep, self-regulatory behaviour, and physical activity. Parents described how children used IEDs for long journeys, before bedtime, and when parents juggled work commitments and housework. Parents also highlighted situations when they preferred to give children IEDs instead of play, as it can be 'less messy' and safer than playing outdoors. Parents from the nursery in the affluent area appeared to have more control over the content of what children watch on IEDs. They observed that control over content was challenging if they had to work from home or had other family members to care for. Parents reported feeling guilty when using their mobile phones around children, noting that it affected family cohesion and that parental modelling was also important. They understood that parents' age might influence attitudes concerning child use of IEDs (i.e. older parents being more restrictive). Parents stressed the need to receive guidance on how IEDs should be used. Some considered that young children had to be taught how to use it earlier.

When taken together, these studies offered a fair understanding of the perspectives of EYPs and parents from high- and low-income communities on IED use. They reaffirmed the need for further research in the field, particularly about benefits and harms.

Theoretical framework

According to the Behavioural Epidemiology Framework, (37) epidemiological studies should be conducted prior to the development and testing of interventions. In particular, associations between behaviours and health outcomes, including dose-response relationships, should be documented to inform population health guidelines before intervention development. This project seeks to provide a better understanding of benefits and risks and offer guidance on the nature of the relationships between IED usage and child developmental outcomes that will inform health guidelines and direct future actions by undertaking a systematic review, followed by a longitudinal study and an ethnographic study.

This project utilises a socio-ecological model (SEM) (38) to capture the multi-level factors that influence children's IED use. The SEM illustrates the importance of networks of people and structures that surround a child (i.e. family, friends, community, culture, policies and systems) to support the child's optimal development (39).

The SEM will frame the systematic review by exploring the correlates of IED use across four levels of the SEM: 1) Individual (child); 2) Interpersonal (parent/carer); 3) Environment (home, childcare and

community); and 4) Policy (government). This will be followed by a longitudinal study which will explore the determinants of IED at different levels of domain, using the outcomes measured in this WP: 1) Individual (i.e., age, biological gender, ethnicity); 2) Interpersonal (i.e., maternal educational, parenting style; parent smartphone addiction); 3) Organizational (i.e., presence of screen viewing policy and hours of childcare attendance). The longitudinal study will also explore the optimal dose of IED for young children. This is grounded by the 'just right' paradigm or the 'Goldilocks Principle' (40), in which we will try to establish whether a 'dose' of IED use exists that maximises benefits and minimises harms, particularly on cognitive and psychosocial devolvement.

Finally, informed by the SEM, the ethnographic study will explore the family context where children use IEDs and the interpersonal relationships among the child and family members that influence IED use. The ethnographic study will also be guided by grounded theory, which aims to understand family interactions and actions through observing events and inquiry into the behaviour to better understand the phenomenon (41).

RESEARCH QUESTIONS

This project aims to answer the following *main* research questions:

1) What are the socio-ecological factors associated with IED use in young children (<6 years)? (WP1)
2) Does the duration and content of children's IED use between the ages of 3 and 4 predict their cognitive and psychosocial development at the ages of 4 and 5? (WP2)
3) Is there an optimum dose (duration) that will enhance the positive effects of IED use on cognitive and psychosocial development while minimising any negative effects? (WP2)
4) What is the context and nature of interactions in which children use IEDs in their home environment? (WP3)

RESEARCH PLAN AND METHODS

Guided by the Behavioural Epidemiology Framework (37) and SEM, (38) the project consists of three work packages (WPs).

WP1 Systematic Review

Aim

The aim of the systematic review is to synthesise the evidence on the correlates and determinants of IED use in young children (<6 years).

Rationale

This systematic review will offer an update of a previously published systematic review covering the correlates of mobile screen media among children aged 0-8 years (42). There are significant changes compared to the systematic review published in 2017:

1) Our systematic review will cover the age range from birth to 6 years old as defined as early years (43), and this being more similar to the age range targeted in our longitudinal study (WP2);
2) We are adding more search terms for population (i.e. young children) and exposure (i.e. interactive electronic devices). We will also include additional databases, such as ERIC, Applied Social Sciences Index and Abstracts, and Sociological Abstracts, that were not covered in the prior review;
3) We will include studies conducted in childcare, which were excluded in the previous systematic review.
4) Similar to the study of Paudel et al., 2017 we will also synthesise the data by grouping the correlated variables according to SEM. However, we will also summarise the data using consistency of association (44), and we hope to perform other subgroup analyses within the quantitative synthesis if appropriate (subject to the provision of suitable studies), including those based on study design, study quality, age group (<3 years and 3 to 6 years) and comparing studies from developed and developing countries.

Finally, the previous review focused on studies published between 2009 and March 2017. We performed a scoping search in PubMed from the 1st of April 2017 to the 22nd of July 2023, and this yielded 5,183 studies, showing the significance of this topic in recent years.

Methods

The systematic review will be guided by the PRISMA statement (45), and the review will be registered in PROSPERO.

Search strategy

A literature search will be carried out using the following databases: MEDLINE, Scopus, Embase, CINAHL, ProQuest, PsycINFO, Web of Science, ERIC, Applied Social Sciences Index and Abstracts and Sociological Abstracts with no date restriction. We will contact our PPI groups (i.e., family and professional engagement groups) to help us with the key terms. We will have two sets of search terms related to population (i.e., young children) and exposure (i.e., interactive electronic devices); we will not include search terms for outcomes as we want to be as open as possible for potential outcome variables.

Eligibility criteria

We will include peer-reviewed quantitative studies (observational or intervention) reporting correlates or determinants of IED use. IED will be defined as any portable screen such as tablets or mobile phones. Only studies in children aged 6 years or less, or studies with parent-child dyads in this age group will be included. However, studies that present data on a wider age range but report data on the age category that fits our inclusion criteria will be included. We will include studies conducted in any setting (e.g., home, community or childcare). We will only include studies published in English.

We will exclude studies in clinical populations (e.g., allergy, asthma, cerebral palsy, cystic fibrosis, autism). We will also exclude qualitative studies, systematic reviews, non-human studies and conference abstracts.

Study selection

Studies identified through database search will be exported to Covidence (www.covidence.org), where duplicates will be automatically removed. This will be followed by two rounds of screening, including the first title/abstract screening and full-text screening. The screening will be completed independently by the PI and another project investigator. Disagreement will be resolved by discussion or consultation with another project investigator until a consensus is reached. The PRISMA flowchart will be used to record the selection process.

Risk of Bias Assessment

Study quality of eligible studies will be systematically assessed against the Critical Appraisal Skills Programme (CASP) checklists appropriate for the study design (46) to appraise the trustworthiness, relevance, and results of eligible studies. Quality assessment will be performed independently by two reviewers, and a third reviewer will resolve any disagreements.

Data extraction

A bespoke data extraction template will be piloted across reviewers. The following information will be extracted: publication details, population characteristics, location (country and study setting), study design, sample size, type and method of assessing IEDs, outcome measures (correlates or determinants), type of analysis and results (i.e., association between IEDs use and correlates or determinants). When the results of more than one regression model were reported, the results from the most fully adjusted model will be extracted. Data will be extracted independently by two reviewers.

Data synthesis

If possible, we will conduct meta-analyses on all identified outcomes, subject to the provision of suitable data, illustrating results via forest plots. We will consider both random- and fixed-effects meta-analyses for each outcome based on clinical and methodological heterogeneity identified *a priori* via Galbraith plots: we will not make *post hoc* decisions based on tests of heterogeneity. For random effects meta-analyses, heterogeneity statistics will also be reported, including Cochran's Q test for heterogeneity, the I^2 statistic (proportion of variation across studies ascribed to heterogeneity) and the τ^2 statistic (an estimate of between study variance), from which prediction intervals may be calculated.

Sensitivity analyses will be conducted for all outcomes to assess the robustness of the derived estimates. Regardless of whether meta-analyses are conducted, a narrative synthesis will be undertaken to integrate the findings guided by Synthesis Without Meta-Analysis (SWiM) (47). Depending on sufficient data, we will subgroup the analysis according to study design, study quality, age group (<3 years and 3 to 6 years) and will compare studies from developed and developing countries.

Correlates of IED use will be broadly classified across four levels of the socioecological model (48): 1) Individual (child); 2) Interpersonal (parent/carer); 3) Environment (home, childcare and community); and 4) Policy (government). We will determine the consistency of association for each IED correlate using the model suggested by Sallis et al. 2000 (44).

Assessment of the quality of the total body of evidence

The quality of evidence for each health or development outcome will also be determined systematically using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework, and the quality of evidence will be categorized into "high", "moderate", "low" and "very low". Two reviewers will also complete this process independently, and disagreements will be resolved, if necessary, by a third reviewer.

WP2 Longitudinal study

Aim

The primary aim is to investigate the temporal associations between IED use (duration and mode) and emerging abilities (i.e. composite score of self-regulation, social development, executive function, language and numeracy) in 3-to-5-year-old children. We will also explore if there is an "optimal dose" (duration) which minimises the harms and maximises the benefits of IED use on emerging abilities.

The secondary aim is to explore the longitudinal association between IED use (duration) and secondary outcomes (i.e. BMI z-score, movement behaviour, motor skills, parent-child interaction and school readiness). Finally, utilising the SEM as a theoretical framework, we will investigate the correlates of IED use (duration) at multi-level factors: individual (gender and ethnicity), interpersonal (maternal education and parenting style), and organisational (childcare policy and attendance).

Methods

Study design

This is a one-year prospective cohort study. The study will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (49).

Sampling and participant eligibility

We will use a cluster sampling approach to recruit school nurseries, day nurseries or childminders (educational units clusters) located in the Council areas of Kirklees, Wakefield, Calderdale and Bradford (West Yorkshire). The sampling frame comprises all children enrolled at these educational units who meet the eligibility criteria.

Children will be eligible to participate if they are between 36 to 48 months old at the time of enrolment, have received parent/carer consent for participation, and the child has provided verbal assent. Children will be ineligible if parents or child do not speak and/or understand English or if the child is clinically diagnosed with a developmental disorder by a medical professional prior to either baseline or follow-up assessments.

Sample size calculation

We base our estimates of the magnitude of the effect of IED duration (hours per day) (see Exposure) on the primary outcome of emerging abilities (EA) measured as a composite score (i.e., self-regulation, social development, executive function, language, and numeracy) assessed by the Early Years Toolbox (see Primary outcome). Our estimate of sample size was based on a proxy study by Kuzik et al. (50) which examined the association between meeting the screen time recommendation (no more than 1 h/day if 3 to 4 years old or no more than 2 h/day if 5 years old) and composite development score, including physical,

cognitive, and social-emotional development. In our personal communication with Kuzik, we were able to clarify the effect size, which turned out to be 0.01 in a model of overall child development and an R-squared value of 0.48 for the multiple regression (which took into account meeting the recommended screen time).

We conducted calculations based on the primary outcome (i.e., EA) under the assumptions of (i) a linear relationship between IED time and EA (following the methods of Kuzik et al. (50)) and (ii) a non-linear relationship with a functional form allowing a turning point or plateauing effect within the range of the data; with the final sample size conservatively estimated to be the larger of these two figures so derived.

For linear modelling, we consider a single independent variable for IED level and two variables for IED predominant mode (educational/non-educational; and age-appropriate/non-age appropriate) (see Exposure), while for non-linear modelling, we consider additional independent variables, such as to model a quadratic term in a polynomial relationship; or two-part piecewise linear functions. Hence, we conservatively assume a total of four test variables under the assumption of non-linear model. We are assuming an intraclass correlation coefficient (ICC) of 0.01. We account for the expected variation in cluster (educational unit) size by calculating the corresponding design effect (conservatively assuming a large coefficient of variation value of 0.65), yielding a design effect factor of 1.118 for clustering (51). We conservatively assume an additional 15 controlling variables (see Controlling variables) to be tested in the model including: (1) age of child at baseline; (2) Female biological sex; (3) Asian ethnicity; (4) Other (non-White or Asian) ethnicity; (5) maternal education above Level 2; (6) authoritative parental style; (7) authoritarian parental style; (8) hours of childcare attendance; (9); parent smartphone viewing addiction score; (10) EA score at baseline; (11) written viewing policy at educational unit; (12) general practice viewing policy at educational unit; (13) educational unit type childcare; (14) educational unit type childminder; (15) proportion of child's local community of child's ethnicity. These variables are partialled out of the independent outcome variables, which we assume follows a multivariate normal distribution.

A sample size of 695 (adjusted for clustering) before attrition loss would achieve 80% power to detect an effect on the EA score at an alpha level of 0.05 for the given effect size. The attrition loss was informed by a 12-month longitudinal study which investigated the associations between electronic application use and media program viewing with cognitive and psychosocial development in preschool children aged 4-5 years (30). The study reported that valid data was obtained from 235 children from 490 approached for recruitment; hence 52.0% attrition (i.e., missing data and children with diagnosed developmental disorders). Further 21.3% attrition was reported between baseline and 12-month follow-up in this study. We anticipate lower rates of missing data in our study, as the exposure (IED use) will be measured by an app (see Exposure) rather than parent questionnaire, we also do subsequent visits to the educational units to recruit children absent on the initial visit; and will offer incentives to encourage completion. Therefore, we are assuming 40% attrition pre-baseline and 15% attrition between baseline and follow-up, bringing to an estimated sample of 1377 children to be screened for eligibility. These values also yield

acceptable case-to-independent variable ratios (52). Sample size calculations were calculated using PASS 2022 (53).

Sample recruitment

We expect to recruit an average of 13 children per school nursery or day nursery and an average of 1 child per childminder, recruiting 51 educational units of each type (i.e., school nurseries, day nurseries and childminders) or 153 educational units in total. We aim to recruit an average of 38.25 educational units from each Council area (Kirklees, Wakefield, Calderdale and Bradford), with the number of units sampled from each Council area being distributed approximately evenly across index of multiple deprivation (IMD) tertiles in each Council. Early Years Public Health consultants in these Council areas will support us in recruiting the educational units (see PPI).

Headteachers, nursery managers and childminders across the study region will be sent study information before telephone contact to invite for participation. We will use posters and fliers in the educational unit to advertise the study with details on the eligibility criteria. Parents of children who meet the age criteria (36 to 48 months) will receive a study information package on how to enrol. Due to the expected variation in the number of children sampled from each unit, we will recruit from institutions sequentially in blocks of no more than six institutions to ensure that approximately equal numbers of each type of educational unit and educational unit IMD are featured when the required sample size is achieved. Each educational unit will receive an incentive of £100 at each time point of data collection, while parents or carers will receive a gift card of £30 at each time point (baseline and follow-up).

Children could withdraw or be withdrawn by parents or carers without affecting care or offering a reason for withdrawing. Data collected before withdrawal will be included in the study analysis unless a parent or carer requests explicitly that their child's data be removed from the database. Cohort characteristics at follow-up will be inspected and compared with baseline characteristics to assess for potential bias. Children who are withdrawn from the study will not be replaced. Participant flow will be recorded on a flow chart as recommended by STROBE guidelines.

Data collection and measures

Data collection will take place when children are aged between 36 to 48 months ("baseline") and one year later when children are 48 to 60 months ("follow-up"). Apart from school readiness which will only be measured at follow-up, all other variables will be measured at both baseline and follow-up. The exact ages of all children at both time points will be recorded on the assessment date.

Exposure

Parents of eligible children who agreed to participate will provide information on the type of IED the child has access to (such as mobile phones and tablets or Android and Apple device). Parents will be asked to download the app Chronicle from the Google Play or App Store on the mobile phone and/or tablet that the child uses. This app, which was developed by Methodic, Inc., in collaboration with the Comprehensive Assessment of Family Media Exposure Consortium (CAFE) (54) gathers data every 15 min from the application programming interface (API), including the app name and its category (such as education,

entertainment, communications) and duration, frequency and time of the day when it was accessed. The research team will export the data to a Chronicle web application for processing. Participants will be asked to delete the Chronicle app once data collection is completed.

If the device is shared with other family members, we will share the recorded data with parents and ask them to confirm which apps were used by the study child from the list of apps we provided. Only apps utilised by the child will be included in the analysis.

Data recorded from the Chronicle app will be processed as IED duration or IED mode as follows:

1) IED duration: We will add the total time in minutes use of IED device by the child across seven days and calculate the average time in minutes per day per child.
2) IED mode: We will record the app classifications based on the category provided by the App Store or Google Play. We will then group these apps in the following categories: a) Educational apps; b) Game apps age appropriate (app is appropriate for 3+ years old); c) Game apps non-age appropriate (app appropriate for 5+ years old); d) Streaming videos age appropriate (i.e., video streaming services set to the age restriction of 5 or less); e) Streaming videos non-age appropriate; f) Others (e.g., video chats, photos, maps).

The mode of IED categorisation will be further combined into time spent: 1) Educational (app educational) vs. non-educational (all others); 2) Entertainment age-appropriate (educational apps, games apps and streaming videos age-appropriate) vs. Entertainment not-age appropriate (game apps and streaming videos non-age-appropriate).

Evidence exists that IED usage in "others" category (item 6 above) is very low (55). Hence any recorded IED usage in this category will be reported descriptively and will contribute towards the measure of IED duration but will not be counted in the assessment of the predominant of IED modes (educational versus non-educational; and age-appropriate versus non-age-appropriate) of IED use.

Primary outcome

The primary outcome is a composite score of the emerging abilities (EA) measured by the Early Years Toolbox (EYT), which has been previously validated for this age group (56). Measures include cognitive, self-regulatory, language, numeracy and social development as follows: 1) Visual-spatial working memory, is the ability to retain and process visual information in memory, and will be measured by the 'Mr Ant' task; 2) Phonological working memory, is the amount of auditory information that concurrently can be coordinated in memory, and will be measured by the 'Not this' task; 3) Inhibition is the ability to control behaviours, urges and impulses, and is measured by the 'Go/No-Go' task; 4) Shifting is the ability to control and redirect attention and will be measured by 'Card Sorting' task; 5) Self-regulation and social development will be assessed by the 34- items questionnaire 'Child Self-Regulation & Behaviour Questionnaire' (CSBQ), which contains subscales to assess cognitive self-regulation, behavioural self-regulation, and emotional self-regulation, but also sociability, prosocial behaviour, externalising problems and internalising problems. The questionnaire will be answered by an early years practitioner at the educational unit who is familiar with the child; 6) Numeracy and mathematical concepts will be assessed

by the 'Early Numeracy' task, which measures numeracy skills, such as numerical language, spatial and measurement concepts, counting, matching digits and quantities, completing number lines, ordinality, subitising, patterning, numerical word problems and equations. 7) Expressive vocabulary will be assessed by the 'Vocab' task and will measure the ability to identify and name objects.

Data will be recorded on an iPad at the educational unit which the child attends. The test is estimated to take 40 minutes. Therefore, to minimise fatigue and maximise attention, the EYT toolbox will be administrated in two separate sessions (minimum of 1-hour intervals) on the same day. A z-score will be calculated for each of the above developmental outcome variables, and the mean z-score for each emerging ability outcome will be used to create a composite score.

Secondary outcomes

The set of secondary outcomes to be considered are based on those analysed in the SUNRISE study protocol, International Study of Movement Behaviours in the Early Years (57). The SUNRISE project currently involves 64 low, middle and high-income countries (58) and started in 2018, with several publications in academic journals showing evidence of the feasibility of the measures (59-61).

The secondary outcome measures considered in the current analysis are as follows:

1) Body Mass Index (BMI) z-score: height and weight will be measured to the nearest centimetre and kilogramme, respectively, using a portable stadiometer and a calibrated scale. BMI Z-scores by age and sex will be calculated according to the BMI reference curves for the UK (62).
2) 24-hour movement behaviour will be assessed by Actigraph GT3X-BT accelerometers. Parents/carers will receive an information pack with instructions on how children should wear the device. Children will be advised to continuously wear the accelerometer on their right hip (including sleeping and during water-based activities) for one week to obtain a minimum of three days of at least 16 hours (63). The accelerometer will provide data on total physical activity, moderate-intensity to vigorous-intensity physical activity, stationary time (categorised as sedentary behaviour since the accelerometer data contains no posture detection) and total sleep.

   The accelerometers will be programmed to record at 30 Hz and downloaded in normal-filtered 15s epochs. The moderate-to vigorous-intensity physical activity (MVPA) and sedentary behaviour is the sum of accumulated 15 s epoch averaged over all valid days. MVPA will be classified as ≥ 420 counts/15 s and sedentary behaviour as ≤25counts/15 s (64), while non-wear time will be defined as ≥ 20 min of consecutive zeros in the accelerometer data (65). Accelerometer data will be analysed using ActiLife 6 Software v6.13.4.

   According to a methodological review, accelerometer attrition rates and compliance with children can vary between 3 to 70% (66). However, in a previous study with members of our group, we reported 80.5% accelerometer compliance (3 days for 8 hours) in children 4 to 5 years old from 26 schools (n=329 children) in the North-East of England (67). With the expertise of our team and the incentive offered, we are confident that we will have a low attrition rate for accelerometer data.

3) Total motor development score will be assessed by the NIH Toolbox (68) and according to the protocols advised by the Motor Domain Group for this age group (69). Four gross motor skills tests will be included: 1) 'Standing long jump' to determine lower body explosive strength (measured in centimetres); 2) 'Supine-timed up and go' which assesses mobility and posture (measured in seconds); 3) 'One-legged standing balance' which measures posture and balance (measured in seconds); 4) 'handgrip dynamometer' which assesses upper body strength (measured in kilograms). Fine motor skills will be measured with the 9-hole pegboard test, which assesses motor dexterity, speed of completion of task (measured in seconds) and accuracy of hand movements. We will report individual scores and calculate a z-score for each individual task, and combine them to obtain the total score.
4) Parent-child interaction will be measured using the StimQ preschool questionnaire (70). The questionnaire has four subscales: 1) reading; 2) parental involvement in developmental advance; 3) parental verbal responsivity; and 4) availability of learning materials. It will be administrated through a parent/carer interview in the educational setting or over the phone. StimQ total scores are calculated by summing up the subscale scores.
5) School readiness: will be provided by the educational unit in an anonymised format in July 2027, when these results are ready before children start formal school (Year 1) in September 2027. School readiness is measured by the early years' foundation stage profile (EYFSP) (71) and assesses five areas of learning (communication and language, physical development, personal, social and emotional development, literacy and mathematics) which are then divided into twelve early learning goals. Teachers score the child's learning goals as 1) emerging or 2) expected. A child is considered school-ready if he/she scores expected for all early learning goals. We will calculate the child's total school readiness score (range 12-24) by adding each learning goal score (range 1-2).

Controlling variables

We will include a few control variables in the analysis. Categorical variables with three or more levels will be modelled using a series of indicator variables. The following variables will be recorded via parent/carer questionnaire:

1) Biological sex: male (reference category) or female.
2) Age in months
3) Individual ethnicity: White (reference category), Asian and other. These categories were defined based on the West Yorkshire Demographics area, which comprises 76.6% White ethnicity, 15.9% Asian and 7.5% other ethnicities (72).
4) Community ethnicity congruence: This variable represents the proportion of residents in the child's postcode region who are the same ethnicity as the child.
5) Maternal education: This will be recorded by asking mothers about the highest level of education and dichotomised as education as Level 2 or below (GCSE or equivalent; or below) (reference category) and Above Level 2 (A level or equivalent; or above).

In addition, due to evidence on the association with screen viewing (73-75) , the following child-level covariates will be included:

6) Parenting style: measured by the Parenting Styles & Dimensions Questionnaire - Short Version (PSDQ-Short Version), which is a 32-item parenting questionnaire which assess the global typology of authoritative, authoritarian and permissive (reference category) (76).

7) Hours of childcare attendance: reported by the educational unit manager.

8) Presence of screen viewing policy at the educational unit: educational unit manager will be asked the following question adapted from the Environment and Policy Assessment and Observation Self-Report (EPAO-SR) (77): "Does your centre have a policy or general practice that pertains specifically to the amount of time children can watch or play or work on a tablet?", with three answer options: 1) Yes, as a written policy; 2) Yes, not written policy but general practice; 3) No policy (reference category).

9) Parent smartphone addiction score, based on the short-form of the Smartphone Addition Inventory (SPAI-SF) of this questionnaire and classified in four components: compulsive behaviour, functional impairment, withdrawal, and tolerance (78).

Finally, to adjust the analysis to the individual EA and to the educational unit type we will include the following covariates:

10) Child baseline EA score.

11) Unit type: school nursery (reference category), daily nursery and childminder

Data cleaning and assessment of missing data

Preliminary data cleaning processes will be conducted before analysis. We will assess whether the values of continuous variables are within range, the plausibility of means and standard deviations, and the validity of coded categories. We will assess data distributions and identify any univariate outliers from graphical methods and from cases with very large, standardised scores disconnected from other scores and multivariate outliers by graphical methods and inspection of leverage/Mahalanobis distances, discrepancy and influence statistics. Any possible errors will be investigated on an individual basis.

We will investigate the extent, pattern and nature of missing data. For small proportions of missing data (below approximately 5% of the totality of the data) which appear to be randomly scatted through the data matrix, we will consider complete case analyses, subject to the absence of evidence for data missing completely at random from Little's χ^2 test and/or separate variance t-tests suggesting data missing at random. If the amount or pattern of missing data precludes complete case analysis, we will consider data imputation. We will use multiple imputations due to their robustness to the type of data missingness. If imputation is conducted, we will conduct sensitivity studies by comparing results derived from data with and without imputation.

Descriptive and exploratory analysis

The sample will be summarised descriptively. We will report the number of children in each educational unit and primary and secondary outcomes by time point (baseline and follow-up). For continuous outcomes, summary information will be presented as means (standard deviations (SD); ranges). For

categorical outcomes, summary information will be presented as frequencies (percentages). We will assess the need for variable transformations to stabilise variance or achieve Normality.

Inferential analysis

The following test variable will be considered for the analysis: 1) IED duration; 2a) IED mode educational; 2b) IED mode age-appropriate.

1) Multilevel regression modelling of primary outcome

We conceptualise a 2–level random intercepts multilevel model, with children clustered within educational units. This model, in which we consider EA at follow-up to be the outcome measure, is designed to answer the primary research questions: How is IED duration (hours per day) and mode (educational vs. non-educational; age-appropriate vs. non-age-appropriate) at baseline, controlling for child-level covariates (including EA baseline scores) and educational unit-level covariates, associated with EA at follow-up in a multilevel model in which children are clustered within educational units?

We will assess the variance partition coefficient (VPC; the proportion of residual variance associated with each level of the model) via a null model before proceeding to a covariate model. We will consider merging the levels in the model if VPC statistics reveal negligible clustering effects (negligible residual variance at the level of the educational unit). We will conduct non-linear multiple regression modelling if there is evidence for a non-linear relationship between level of IED usage at baseline and EA at follow-up, allowing for a single maximum (corresponding to optimum levels of baseline IED usage) or plateau; otherwise, we will conduct linear regression models. If data indicates an optimum IED level of usage associated with a specific maximum value of EA score at follow-up, we will consider alternative non-linear functional forms with maxima or plateauing features, including polynomial (e.g. quadratic) and logarithmic forms; and piecewise functions. We will compare the fit of multiple distributions in the vicinity of any turning point and select the best fitting model in this region to maximise the accuracy with which the maximum value of EA may be obtained. We will fit confidence intervals around the function to derive a range of values for the maximum value.

We will conduct both non-fully adjusted and adjusted models, with adjusted models adjusted for all covariates at each level of the model. Non-adjusted models will include (i) the single determinant of the level of IED usage (duration) at baseline, (ii) the determinants of IED predominant mode at baseline (as defined above), and (iii) determinants of IED duration and mode. These determinants will all be added in at the *child* level of the model. To capture any differential effects in assessing levels of IED usage with differing predominant modes of use, we will include first-order interactions within unadjusted models. Any interaction revealed to be of substantive importance will be retained in a re-cast model alongside all main effects. Adjusted models will be based on the included variables of both IED duration and IED predominant mode, any interactions of substantive importance and all controlling covariates at the appropriate level of the model. We will not use automated modelling strategies for variable selection and will retain all main effects in the adjusted model. However, we will assess collinearity in adjusted models

and consider deletion of controlling covariates if excessive collinearity is apparent (variance inflation factor >=5 for any variable).

2) *Multilevel regression modelling of secondary outcomes*

We will conduct multiple linear regression modelling on all numerical secondary outcomes and multiple logistic regression modelling for the binary secondary outcome measure, using the same model structure as for the main analysis of the primary outcome. If any evidence is revealed for non-linearity between the level of IED duration and the secondary outcomes, we will consider non-linear modelling for the analysis of the primary outcome; else, we will consider linear modelling. In both cases, we will adjust for the same set of covariates and interactions defined for the primary outcome. No adjustment for multiple analyses will be made; however, all analyses will be planned a priori and reported in full.

3) *Multilevel regression modelling: subsidiary analysis*

To explore the socio-ecological correlates of IED duration at the individual (gender, age and ethnicity), interpersonal (maternal education, parenting style and smartphone addiction), and organisational (childcare policy and attendance) levels, we will conduct a subsidiary analysis, considering the above set of variables as determinants of IED using the variables that are reported as controlling variables.

We will conduct random intercepts and multiple linear regression modelling on the outcome of IED duration at baseline. A 2-level hierarchical structure will be used, with variables designated as Individual or Interpersonal attached at the lower (child) level and variables designated as Organisational attached at the upper (educational unit) level.

Any relationships revealed during this process will be used in future modelling to generate hypotheses within a wider structural equation modelling framework.

4) *Sensitivity analysis and data reporting*

For the primary outcome, we plan to conduct sensitivity analyses to assess the sensitivity of the model to certain assumptions, as mentioned above. We will compare parameter estimates of tested variables in unadjusted and adjusted models. For the multilevel modelling of the relationship between IED duration and EA, we will conduct both random slopes and random intercepts models and assess variation in slopes between higher-level units. If data imputation is viable, we will run models with and without imputed data (see 'Data cleaning and assessment of missing data').

For linear and non-linear regression models of continuous numerical outcomes, in the main and subsidiary analyses, we will report all unstandardised parameter estimates with associated 95% confidence intervals and *p*-values. For logistic regression models, we will report all odds ratios with associated 95% confidence intervals and *p*-values. If evidence is revealed for a non-linear trend, we will report the functional form of the best-fitting curve and identify the location of any maximum or commencement of plateauing effects. We will check all regression modelling assumptions, including homogeneity of variance and normality of outcome variables for each value of an independent variable, using residual analysis. Statistical analyses will be conducted using MLwiN version 3.06 (79) and Stata version 17 (80).

WP3: Ethnographic study

Aim

To understand the social, familial, and environmental context in which young children use IEDs.

Methods

Study design

This is a qualitative study which will take a pragmatic approach (81) to develop a broader understanding of IED use based on observation and inquiry. We will use video-reflexivity ethnography (VRE), which will capture the routine behaviours and interactions of children using IED in the home setting (video-ethnography), augmented by an interview to explore these behaviours with parents (video-reflexivity) (82). The video recording will provide data on the practices and behaviours of young children concerning IEDs (83). It provides access to non-verbal communications (84) and offers information on the interplay of multiple communication channels (85). Involving parents/carers in interpreting the observations will also increase the visibility of verbal and non-verbal communications of the child and enable us to reflect on the interactions that children directly experience (86).

Recruitment

Families must have a child between 3-5 years with no developmental disorders to be eligible to participate. Families will be recruited via daily nurseries, with the assistance of the Local Authority project partners, the Early Years Public Health consultants (see PPI). We will select two daily nurseries in the highest IMD quintile and two from the lowest IMD quintile from the West Yorkshire region.

Nursery managers will be sent the study information before telephone contact. We will promote the study via posters and fliers in the nursery setting. All parents/carers of children between the ages of 3 and 5 will also receive the study information packet, which includes instructions on contacting the research team to participate in the study and we will be doing a short presentation at the nursery to parents/carers to explain the study.

Twenty parents/carers will be invited (10 from nurseries in low-income areas and 10 from nurseries in high-income areas). To have a better understanding of participants demographic we will collect information on participants' age, gender, ethnicity, marital status, parenthood and years of education.

According to a recent systematic review sample sizes in qualitative research (87), 9 to 17 interviews are adequate if the study population is reasonably homogeneous. Others, however, believe that sample size for thematic analysis cannot be fully determined in advance of analysis (88). Taking a pragmatic approach, we believe that this number would be sufficient to reach saturation. In appreciation for their participation in the study, parents and carers will be given a £100 gift card.

Data collection, processing and analysis

Video capturing can be time and resource-intensive and may cause changes in behaviour due to observation (89), other than privacy concerns (90). We will address these concerns by involving parents before the study begins through our family engagement meetings (see PPI), where we will discuss issues such as participant rights, anonymisation, protection, and material usability.

We will place a video camera at the participants' home for seven days. However, we will set the camera to record on the last 3 days (2 weekdays and 1 weekend) to reduce children's self-consciousness of the data. The researcher will discuss with parents/carers the best area to place the camera in one room where the child spends most of their time. We will request that parents turn on the cameras while their children are in the room and turn them off when they are not in order to lessen the intrusiveness of family ethnography (91). When an inappropriate recording occurs, parents might request that we remove that particular session.

The entire video will be watched by a member of the study team, who will then edit and delete the parts when the child is not present. We are planning to choose no more than ten 3-minute-long video clips, and we will base our choice on footage of the child interacting with IEDs and other families' or friends' members. The PI and RA will watch the video segments and reflect on the question, "What is 'this' an example of?" and develop themes using an open-coding approach (92). Researchers will attempt to interpret video material by inferring the meaning of an event rather than describing the event (93).

These video clips will then be shown to the parents/carers in a reflective semi-structured interview, in which parents/carers will have the opportunity to provide their understanding of what is happening in the video footage. The discussion will be steered by an interview guide with open-ended questions and reflective listening. To promote reflexivity, we will pause the video at particular points and prompt participants with questions like: "Can you tell me more about this moment?"; "What do you think is going on here?"; "Can you tell me how others in the video footage are reacting to it?". We will also try to explore other aspects beyond what is being seen in the video, such as: "Based on your experience, what does the use of IEDs by the child bring to him/her?" "What does it bring to the family (dynamics, routine)?". Interviews will last approximately 60 minutes each.

Interviews will be digitally recorded with participants' consent and transcribed verbatim, and all identifiable information will be removed. Each patient will be given a pseudonym to ensure confidentiality. The transcript data will then be imported into Nvivo 12. The transcripts will be read to understand participants' meanings and perceptions, and codes will be attached to text segments. We will use inductive thematic analysis to interpret the data (94). We acknowledge that preconceived ideas and the researcher's knowledge and experiences of the subject area might influence the developed themes (95). To overcome this challenge, the PI, a RA, and one of the co-applicants (PB or KA) will independently conduct the thematic analysis, and researchers will convene to discuss these themes. Likewise, we will provide extensive quotations from participants to allow readers to formulate their understanding of the themes (96).

Data from the video-ethnography and video-reflexivity interviews will offer an in-depth understanding of the contextual use of IED by the child and the perceptions of parents/carers, which will allow the researchers to elaborate a framework that enables the understanding of IED use by young children in the social and familial environment.

PROJECT MANAGEMENT

Prof Liane Azevedo (LA) will be responsible for the overall management of the project, including liaison with co-applicants, collaborators, research assistants and funder. LA will be supported by experienced co-investigators on each WP: 1) WP1, a systematic review, will be co-led by Prof Elizabeth Goyder (EG); 2) WP2, a longitudinal study, will be co-led by Prof John Reilly (JR), Prof Tony Okely (TO) and Prof Stuart Fairclough (SF); 3) WP3, an ethnographic study, will be co-led by Prof Paul Bissell (PB) and Prof Kathryn Almack (KA).

The project team also includes experts in biomedical statistics, Dr John Stephenson (JS), developmental psychology, Dr Jenny Retzler (JR) and early years physical activity, Dr Dan Jones (DJ).

Three post-doctoral Research Assistants (RA) will also assist with the study. RA1 will manage the three WPs and run the project on a day-to-day basis but supervised by LA. RA2 will support WP2 and WP3, while RA3 will run WP3. Additionally, a project administrator will support the project team, plan meetings, communicate with stakeholders, and support outreach efforts.

We will convene two support groups to guide and manage the study:

1) A Project Management Group (PMG) which will meet monthly and chaired by LA. The PMG will include the co-applicants, and the research assistants. It will monitor all aspects of the project, discuss progress, challenges and solutions to ensure that the project is conducted to the rigorous standards. Meetings will be minute with action points, timelines and persons responsible identified.
2) A Project Steering Group (PSG) will meet twice a year. The group will consist of an independent chair from the Office of Health Improvement and Disparities (OHID), Gemma Mann; one independent expert, Prof Jane West from NIHR CRN and Born in Bradford; a representative from Ofcom on children's media literacy, Evie Owen; policymakers from the four local authorities involved in the project (n=4); representatives from the family (n=2) and professional (n=2) engagement groups; and members of the project team (n= 3, PI, one Co-app and PPI lead).

   The PSG will provide the overall supervision of the project, ensure that the project is conducted to rigorous standards, and offer recommendations to the PMG. We will formalise a Terms of Reference, including membership, responsibilities and reporting mechanisms. In the first instance, the PSG will act as the Data Monitoring Committee (DMC) to ensure that the project is undertaken rigorously and on time. However, a separate DMC will be established if this is recommended by the PSG. Minutes and actions of the meetings will be recorded and kept on file.

ASSESSMENT OF RISK

We will conduct a study risk assessment to identify potential risks and mitigation approaches. If adverse events occur during data collection of the longitudinal (WP2) and ethnographic (WP3) studies, this will be recorded in detail along with preventive actions. If necessary, changes in project directions will first be discussed with the PMG and PSG. We will then discuss this with the chair of the ethics committee and funder (i.e., NIHR).

Children and adults participating in WPs 2 and 3 can withdraw from the study at any time. If, during the data collection of WP2, a child becomes distressed, the researcher will seek a member of staff at the educational unit who can engage the child with the relevant welfare systems in place within the educational unit. If a researcher becomes aware of a safeguarding issue concerning a child, they will immediately inform the relevant staff member within the participating educational unit so that safeguarding procedures can be followed.

ETHICS

The study will comply with the Economic and Social Research Council's (ESRC) research ethics framework. Ethical approval will be sought for all aspects of the work from the Sheffield Hallam University Ethics Committee. The ethical approval process for WP2 will start in July 2024 in order to obtain ethical approval by October 2024 (or earlier). We will seek the written consent of the educational unit (daily nursery, school nursery, and childminder) managers for their setting to be involved. All researchers in the project will work in accordance with the educational unit safeguarding policies. Early years practitioners involved in the project (i.e., WP2 questionnaires) will also be asked for their written consent. We will request informed written parental/carer consent while children give their verbal assent to participate.
The ethical approval process for WP3 will start in January 2025 in order to obtain ethical approval by July 2025 (or earlier). In WP3, we will seek all family members' written consent and ask for the children's verbal assent.

PROJECT TIMETABLE

The project will commence in May 2024 and last for 48 months. The systematic review (WP1) will be completed in approximately one year (May 2025). Data for the longitudinal study (WP2) will be collected between 9-33 months, and results will be known by month 38 of the project (May 2027). Data for the ethnography study (WP3) will be collected between 18-24 months, and findings will be available by month 30. A detailed timeline of the project is included in Figure 2.

DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

Our dissemination plan will be informed by our discussions with the PMG and PSG groups. We will host Knowledge Café events, for which we will invite parents, EYPs, community members, and representatives from government organisations. We will do two events, each of around two hours in duration, with 20 participants each. The Knowledge Café has been widely used to stimulate deliberative dialogue to encourage participants to share their knowledge and experiences, facilitate knowledge exchange and generate new knowledge (97). The project team will put together a general briefing, explaining the event's objectives, and how it will be conducted and inform the project findings. Participants will be invited to form groups of six for subsequent discussions. The discussions will be facilitated by members of our research

team, who will encourage participants to share their ideas on topics in which we need input from the relevant stakeholders. After a 60-minute discussion, participants will be invited to a plenary session to share their group insights and ideas. The information will be recorded and transcribed. The transcripts will be summarised to refine the project theory and the policy brief. Summary infographics and information on plans will support the policy briefs. They will be distributed to policymakers and key stakeholders (e.g., Yorkshire & Humber Public Health Network, Education and Health and Social Care Committee in the House of Commons and Ofcom). We will use our network through the Practice and Research Collaborative within Yorkshire and Humber (PaRC) to share learning and disseminate our findings to other local government areas.

We will also provide newsletters to childcare, schools and childminders using visual representation (e.g. infographics and comics) and disseminate findings through social and local media.

We expect to publish at least five scientific publications in open-access peer-reviewed journals. The study findings will be presented at international conferences such as the International Society of Behavioural Nutrition and Physical Activity and the European Conference of Public Health. We will also share our findings with Comprehensive Assessment of Family Media Exposure Consortium (CAFE) (54) which is an international group of cross-disciplinary collaborative researchers based on a shared interest in improving the quality of media measurement tools, with the aim of expanding data analytics and integration.

Finally, although this project is not aiming to develop an intervention, it adheres to the fundamental principles of the MRC framework for complex intervention (98) by developing, refining, and testing theory, identifying key uncertainties, considering context and engaging with stakeholders. All of these steps will contribute to the development of new health guidelines and potential interventions. Therefore, to carry out the early-stage development of the intervention, we intend to apply it to the MRC Public Health Intervention Development (PHIND) Programme in the future.

PROJECT EXPERTISE

This is a multidisciplinary team that includes academics from eight different institutions. The project team spans the disciplines of public health, epidemiology and social science. Together, the team brings expertise in systematic review and meta-analysis (EG, MC, JS, LA), observational studies (SF, TO, JR, DJ, JS, LA), qualitative research (PB, KA), biomedical statistics (JS), early childhood behaviour (TO,JR,DJ, BP, LA), health inequalities (PB, LA), sociology of family lives (KA) and socio-emotional and cognitive development (JR). We have built strong collaborators with the Early Years' Improvement officers from Bradford, Calderdale, Kirklees and Wakefield Local Authorities. The Local Authority team helped us develop the project ideas and will serve as PSG advisors. We also have the support of the NIHR CRN, with support from Prof Jane West, the NIHR CRN National Specialty Lead for Public Health, who led the Born in Bradford project. The Office of Health Improvement and Disparities (OHID), shapes and drives health priorities for the government through Gemma Mann, the Health and Wellbeing Manager of

Yorkshire & Humber. Finally, we have the support of Ofcom, who closely monitors communication changes and how communication devices are used, through Deborah McCrudden, Director of Market Research.

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