Parent-Administered Screen Time Intervention (PASTI): A Feasibility and Pilot Randomised Control Trial in Toddlers

End of Grant Report for the Nuffield Foundation

29th August 2024

Authors

Hannah Pickard[1], Petrina Chu[2], Claire Essex[1], Emily Goddard[1], Ben Carter[2], Rachael Bedford[3,4] and Tim J. Smith*[1,5]

[1] Centre for Brain and Cognitive Development, Birkbeck, University of London

[2] Institute of Psychiatry, Psychology and Neuroscience, King's College London

[3] Department of Psychology, University of Bath

[4] Department of Psychology, Queen Mary University of London

[5] Creative Computing Institute, University of the Arts London

* Corresponding Author:

Tim Smith, Professor of Cognitive Data Science. Email: tim.smith@arts.ac.uk

The first and corresponding authors acknowledge responsibility for framing this overall report.

Acknowledgements

We are grateful to the Nuffield Foundation for funding this project (Grant number: FR-000022056; "Parent-Administered Screen Time Intervention (PASTI): A feasibility and pilot RCT"). The Nuffield Foundation is an independent charitable trust with a mission to advance social well-being. It funds research that informs social policy, primarily in Education, Welfare, and Justice. It also funds student programmes that provide opportunities for young people to develop skills in quantitative and scientific methods. The Nuffield Foundation is the founder and co-funder of the Nuffield Council on Bioethics, the Ada Lovelace Institute and the Nuffield Family Justice Observatory. The Foundation has funded this project, but the views expressed are those of the authors and not necessarily the Foundation. www.nuffieldfoundation.org

We are grateful to our Early Years Stakeholder Panel and our Advisory Board Members for sharing their expertise with us in meetings and beyond: Melanie Pilcher, Charlotte Whalley, Jennifer Holly, Maxine Palmer, Helen Rutherford and Gillian Harris. We are also grateful to our Trial Steering Committee Members: Will Mandy, Joana Carvalho Vasconcelos, Anna Joyce, Kerry Davies and Evelyn Tong for their support and guidance throughout the trial. We would like to thank our placement students and volunteers: Katie Baulcombe, Jemima Cowley, Qiaoyu Zhou, Zoe Howell and MSc project students who helped with data collection. We would like to say a special thanks to all the children's centres who supported our recruitment and the families who took part in our trial, without you none of this would have been possible.

Contents

Executive Summary

Background: Toddler screen time is increasingly common due to the availability of digital devices in the child's environment, their portability, attractiveness, and intuitive interfaces, e.g. smartphones and tablets. The intense sensory-cognitive stimulation provided by digital devices during this peak period of neurocognitive development has led to recommendations for toddler screen time to be severely limited, especially during key parts of the day including in the hour before bed. These recommendations are supported by correlational evidence including associations between greater toddler screen time, poorer sleep and attention. However, to-date no studies have shown that screen time is causing poorer sleep and attention by intervening on toddler's pre-bed screen time. Understanding the causal impact of screen time on early development is of the highest importance to inform parents, practitioners and policy makers about early-years digital technology use.

Project aims: Our Parent-Administered Screen Time Intervention (PASTI) randomised controlled trial (RCT) had two main aims: To assess 1) *Feasibility* – is it feasible for parents of toddlers to remove screen time in the hour before bed and complete our intervention? and 2) *Preliminary efficacy* – does the removal of screen time before bed improve toddler sleep and attention?

Methods: This assessor-blinded, UK-based RCT was conducted between July 2022 and July 2023 at the Centre for Brain and Cognitive Development (Birkbeck, University of London). 427 families were screened, 164 were eligible (38.4%; 16-30 months; ≥ 10 minutes screen time on ≥ 3 days/week) and 105 families were randomised (60 male, mean age=23.70 months). Families were randomised (1:1:1) to 1) PASTI: caregivers removed toddler screen time in the hour before bed and used activities from a Family Bedtime Box instead (e.g. reading, puzzles); 2) Bedtime Box-only (BB-only): used matched pre-bed activities, with no mention of screen time; or 3) No Intervention (NI): continued as usual. The feasibility outcomes included participation rate, intervention adherence, retention, family experiences and assessment

acceptability. The efficacy outcomes included screen use, objectively-measured sleep and eye-tracking attention measures.

Findings: The trial was feasible, with 99% retention and 94% of families adhering to PASTI. The PASTI group showed moderate-to-large reductions in parent-reported screen time. Further, PASTI showed small-to-medium improvements in objectively-measured sleep efficiency and night awakenings compared to NI and BB-only, as well as reduced day-time sleep compared to the NI group. There was no observable effect of PASTI on objective measures of attention. In the BB-only group, parents reported an increase in children's effortful control and inhibitory control abilities, while PASTI parents reported no improvement following the intervention.

Conclusions: Supporting current early-years recommendations, caregivers were able to remove their toddler's screen time in the hour before bed and doing so produced modest preliminary improvements in toddler sleep. No effects on objectively measured attention were observed. PASTI is a low-cost, easy-to-implement intervention that is inclusive of diverse family profiles. These pilot efficacy findings require replication in a fully-powered confirmatory trial. Future trials are needed to determine which aspects of the intervention (bedtime box, text messages, etc) are critical. Despite clear measurement strengths, the current study is limited by parent-reported screen use, which may be subject to reporter-bias; the field critically requires methods for unobtrusively capturing toddlers' multi-screen exposure. Future studies must also engage with the rich variety of toddler screen use (e.g. types of content, context of use) and differing neurodevelopmental profiles that may moderate the impact of removing pre-bed screen time.

Background

Over the last decade there has been a rapid increase in childhood screen time (e.g. TV, tablets and smartphones; Ofcom 2023) and this increase has been linked to poor sleep (Cheung et al., 2017) and differences in attention in toddlers (Portugal et al., 2021a, 2021b). Sleep and attention are two critical predictors of childhood health and cognitive development. Therefore, understanding the potential causal impact of screen time on toddler sleep and attention is of the upmost importance. Current screen time guidelines for toddlers in the UK recommend no screen time before bed (e.g. Royal College of Pediatrics and Child Health, RCPCH), yet there is a critical need for causal evidence. Here, we conduct a pilot and feasibility randomised controlled trial where parents intervene on their toddlers' screen time in the hour before bed to examine the direct impact on sleep and attention.

Sleep is important for brain maturation (Lam et al., 2021) and poor sleep can have a significant impact on child development, leading to detrimental health outcomes in later childhood and adulthood (Gangwisch et al., 2010; Gradisar et al., 2013). Research has shown that higher screen exposure is associated with sleep problems (Carter et al., 2016), and this association has been reported to be greatest immediately before bed (Mireku et al., 2019). Correlational associations are supported by interventions in adults showing that watching screen content has a direct causal impact on sleep, when compared to matched non-screen content (Chang et al., 2015). Furthermore, a recent meta-analysis of studies removing screen time as part of a suite of other behavioural changes in older children suggests that screen removal has small improvements on sleep duration and sleep onset (i.e. falling asleep quicker; Martin et al., 2021). However, whether increased screen use in isolation has a causal impact on sleep in toddlers is unknown due to a lack of high-quality evidence.

Poor sleep is also commonly associated with attention. Reduced concentration is thought to follow insufficient sleep (Hoyniak et al., 2015) and difficulties falling/staying asleep is common in children with attention problems (Stein, Weis & Hlavaty, 2012). Exposure to screen content across development has been linked with later attention problems (Law et al., 2023; Lillard & Peterson, 2011; Nikkelen et al., 2014). In our previous Toddler Attentional Behaviours and Learning with Touchscreens (TABLET) study, we used gaze-contingent eye-tracking paradigms to measure toddlers' attention and found that 18-month-olds with higher touchscreen use show enhanced saliency-driven attention (e.g. quicker to find the 'odd-one-out') and reduced goal-directed driven attention (Portugal et al., 2021a, 2021b). These findings highlight potentially important developmental changes in attention that need further investigation. The resources required to inhibit distraction are most diminished in the evening, making it harder for toddlers to ignore background screens; the hour before bed is thus a key time for interventions to target.

Previous parent/child education interventions in children have been successful in reducing screen time (Schmidt et al., 2012; Wu et al., 2016). Some studies have shown that screen time interventions are particularly effective when behaviour substitution aids are used (Lewis et al., 2021). A recent intervention study in preschoolers found that an 8-week parent education screen time intervention reduced parent-reported screen time, attention problems and increased sleep quality, compared to a control group (Lin et al., 2021). Furthermore, objective experimental methods to capture sleep and attention are important to ensure that effects observed are not influenced by biases in parent-report as a consequence of parent knowledge about the intervention.

Parents are often gatekeepers for toddler screen use (e.g. switching on the TV) and so the potential impact via parent-administered interventions is high. Screen exposure may act directly to reduce sleep duration/quality (e.g., melatonin suppression by blue light; Chang et al., 2015) and attention control (e.g. attention suppression; Lillard & Peterson, 2011), or indirectly, through displacement of other bedtime activities (e.g. play, story-time, bath; Gentile, et al., 2017) Teasing apart these hypotheses requires comparison between an intervention that alters screen time before bed and one that encourages similar routine pre-bedtime activities without altering screen time.

Aims and objectives

The study aimed to assess 1) the *feasibility* and *preliminary efficacy* of a 7-week Parent-Administered Screen Time Intervention (PASTI), compared with a Bedtime Box Intervention (BB-only) and No Intervention (NI), in 17-to 31-month-old toddlers who have parent-reported screen time in the hour before bed. Preliminary effects of the intervention on attention and sleep were objectively measured.

Methods

The full trial protocol including all methodological details and materials used in the trial are available via our trial pre-registration on Open Science Framework (https://osf.io/vnt6k/?view_only=a6e74c6fa7314325a1779451f3a86d91). The trial was registered for an International Standard Randomised Controlled Trial Number (ISRCTN58249751, Registered 29/04/22; https://doi.org/10.1186/ISRCTN58249751) before data gathering commenced.

We conducted a three-arm randomised controlled trial in toddlers. The study took place in the Centre for Brain and Cognitive Development (CBCD; “Babylab”) at Birkbeck, University of London (lab assessments) and in families’ homes (home assessments). Researchers blind to intervention group collected all baseline and follow-up measures.

Participants

We aimed to recruit 105 families with a child between 16 and 30 months at enrolment. A sample size N=105 (N=35/group) has been shown to be sufficient to estimate the key unknown parameters necessary to power a full confirmatory RCT (Teare et al, 2014).

Inclusion criteria: 1) aged 16-30 months at pre-screen (enrolment); 2) live in Central/Greater London and surrounding areas (within 75 miles of CBCD); and 3) the child must have 10+ minutes of caregiver-reported screen time in the hour before bed on at least 3 days/week.

Exclusion criteria: 1) a genetic or neurological condition; 2) premature birth (less than 37 weeks); and 3) already participating in another trial or research study.

Families who took part in our trial were given a £30 voucher after their first lab visit and a £50 voucher after their second visit as a thank you for their time and participation.

Recruitment

Recruitment began in Spring 2022 and the trial was completed in Summer 2023. A cover story for PASTI was used to obscure the role of screen time to avoid self-selection of families who would be interested in the topic and to minimise any bias in caregiver-reported screen use: Families were recruited into our "**Bedtime Boost**" trial on toddler bedtime activities in the hour before bed. To ensure we reached a diverse group of families, we recruited from the following places 1) Centre for Brain and Cognitive Development (CBCD) Babylab Database; 2) Social media platforms including those of our charity partners: the Early Years Alliance (EYA), the National Childbirth Trust (NCT) and The Sleep Charity; 3) the NCT membership database and 4) children's centres, nurseries and libraries across London and surrounding areas.

Recruitment challenges

Initially, (May-June 2022), we advertised Bedtime Boost to families with a 16- to 18-month-old child and offered a £30 voucher as a thank you for participating. Over this initial 8-week period of advertising **13.5 families per week** expressed interest in participating and only 2 families were booked for a Babylab visit. This recruitment rate would have made the trial unfeasible. We therefore decided to make two significant changes. First, **we increased the upper age limit for our study to 30-months-old**, as we had received a great deal of interest from families with older children and our prior research had demonstrated similar associations between screen time and attention (Portugal et al., 2021a; 2021b) and sleep (Cheung et al., 2016) across this age range. Second, **we increased the compensation voucher amount from £30 to £80**. An £80 voucher was chosen to be equivalent to minimum wage for the time

committed across home (~5 hours) and lab (~4 hours) activities by the PASTI group. This increase was supported by feedback from similar studies at Birkbeck Babylab and from children's centre staff who believed it would demonstrate the degree to which we valued participant's time, especially those from disadvantaged backgrounds who are typically under-represented in such research. After introducing these changes, we received an approximate four-fold increase in sign-ups: **52.75 families per week**. After only 4 weeks, 34 families had booked in their Babylab visit.

Intervention

We co-designed a 7-week **Parent Administered Screen-Time Intervention (PASTI)** that required caregivers to remove screen time from their child (aged 17-to-31 months old) in the hour before bed. The PASTI is modelled on effective parent-education screen time interventions in older children (see Schmidt et al., 2012 for review).

Intervention material development

Figure 1: Intervention co-creation. Left: the PASTI team and early-years stakeholders cocreating the materials. Right: Lists and problems that might arise during the intervention and potential solutions.

All PASTI materials and support structures were created through an iterative process involving two co-creation workshops with Early Years Stakeholders (e.g. parent practitioners). Together with Flow Associates, we designed the agenda and facilitated the workshops. During the first co-creation workshop, we discussed 1) how to help families remove screens; 2) how to communicate and deliver the intervention to families; 3) how to maximise parent engagement and 4) which materials we need to help families replace screen time. Based on these discussions, together a consultation focus group with caregivers of a one-year-old we developed materials and presented these at a second co-creation workshop. Only materials that received a majority vote were used in the trial. In addition, we shared the full timeline of the trial including all main contact points with caregivers (e.g. phone calls) and our early years experts helped us to design the content and structure of these conversations.

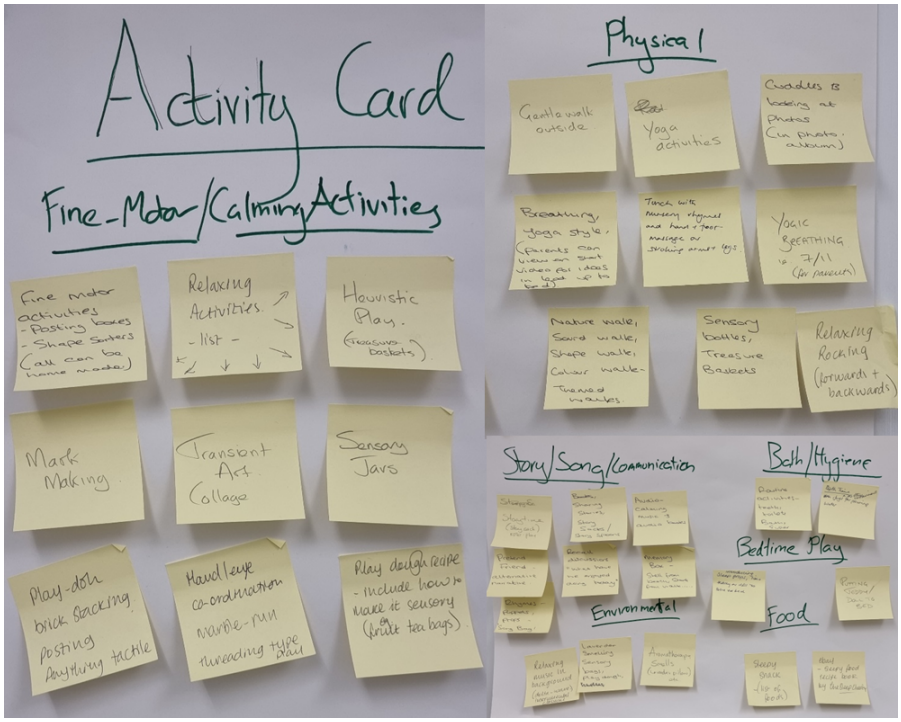

Figure 2: A list of ideas for our Bedtime Box activity cards co-created by our early years stakeholder panel.

PASTI Intervention

Families received a booklet to educate them on "No screen time in the hour before bed" and a Family Bedtime Box with tips on alternative pre-bed activities to help displace pre-bed screen time (e.g., activity cards with fun bath games, story time ideas, as well as a selection of age-appropriate toys, such as crayons, a bath toy, puzzle etc.; see Figure 3). Caregivers were asked to use toys/activities from the Family Bedtime Box with their child in the hour before bed. Every week, caregivers received a check-in message that contained new suggested activity card ideas to promote continued participation in the trial.

Figure 3: An artist's rendering of the Family Bedtime Box, its contents and the activity cards.

During the first week of the intervention, families were invited to take part in a short (5-15 minute) phone/video call with an unblinded researcher to reflect on their strategies for removing screen time in the hour before bed and discuss any challenges that they may have faced.

Intervention comparison groups

To examine the direct impact of screen exposure in the hour before bed on children's sleep and attention, the PASTI group was compared to two other modes of delivery, including a **Bedtime Box group** and **No Intervention** group.

Families in the **Bedtime Box group** received identical materials to the PASTI group (i.e. Family Bedtime Box), but *without any screen time guidance.*

Families in the **No Intervention group** did not receive a Family Bedtime Box or any instructions to change their child's activities or avoid screen time in the hour before bed. Instead, they were told to continue with their child's pre-bedtime activities as usual.

Procedure and data collection

All families who were eligible and provided informed consent were invited to take part in our study. The procedure for trial participation is illustrated in Figure 4.

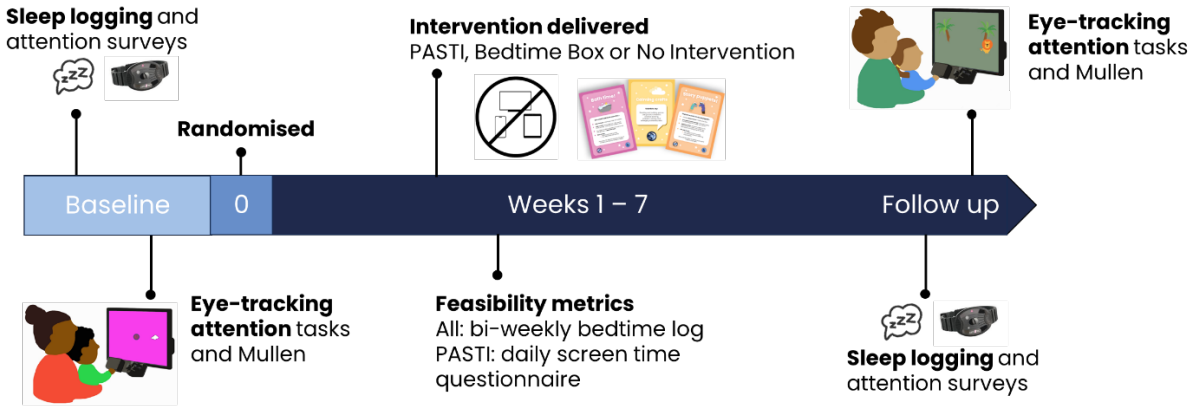

Figure 4: Week-by-week schematic of the flow for participants through the trial. See details for each stage below and in the pre-registered trial protocol.

Baseline and follow up assessments

Home activities

Families completed a series of baseline assessments over a two-week period before being randomised into one of our intervention groups. First, caregivers completed **a series of questionnaires** about their child's sleep, behaviour, attention, global development, daily activities and their own levels of anxiety (see our full trial protocol on OSF for further details). Second, caregivers completed a bi-weekly **Bedtime Activity Diary** to tell us about their child's activities in the hour before bed (e.g. screen use, play).

Caregivers were also asked to capture a measure of their child's sleep over a 6- to 9-day period using an **Actigraphy** watch (MotionWatch 8, CamNtech) and **Sleep Diary** (Sadeh, 2004). Actigraphy is a reliable and valid method for naturalistically measuring sleep in children, with research showing >80% agreement with gold standard measures of sleep such as polysomnography (Sadeh et al., 1995). The Actigraphy watch is designed to measure movement and after applying a threshold determines whether the child was asleep vs. awake based on their level of movement in small time periods (e.g. 15 seconds).

All baseline home activities were repeated for **follow-up** during week six and seven of the trial, prior to the families' second Babylab visit (see the participant timeline).

Lab activities

All lab-based activities took place in the Birkbeck Babylab. Lab activities were run by **blinded researchers**, prior to randomising families to their intervention group. Children took part in three eye-tracking experiments, using an EyeLink 1000 Plus eye tracker. The Visual Search Task, Anti-Saccade Task and Gap-Overlap Task are designed to measure visual attention (see full trial protocol on OSF for further details). In the Visual Search Task (see Figure 5), the time taken for toddlers to spot a target red apple among distractors is recorded. In the Anti-Saccade Task (see Figure 6), toddlers first look at a central stimulus, a black spot then appears on the left or right of the screen, in the child's periphery. They must ignore this distractor and instead look to the opposite side of the screen to locate the target animation (a jungle animal + sound); time to look at the distractor (pro-saccade) and the number of eye-movements towards the target animation (anti-saccade) were recorded. The Gap-Overlap Task (see Figure 7) measures attention flexibility; the time taken for toddlers to shift their attention from a central stimulus to a peripheral stimulus is measured.

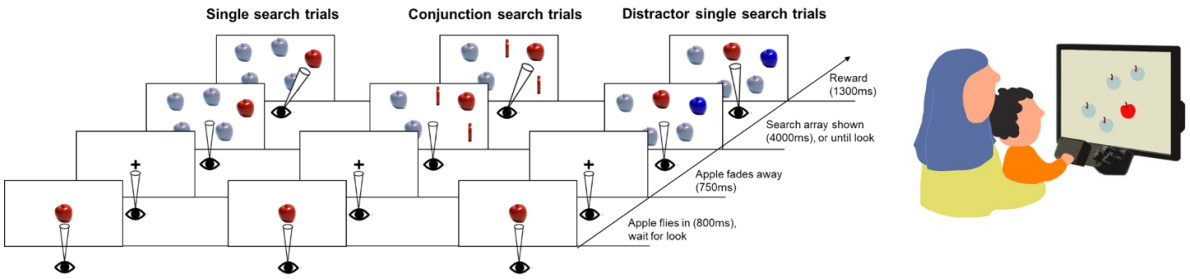

Figure 5: Schematic of the procedure for the Visual Search Eye tracking task across three trial types: Single search (aka "pop-out"), Conjunction search and Distractor search. In all trials the participant was rewarded for looking at the red apple.

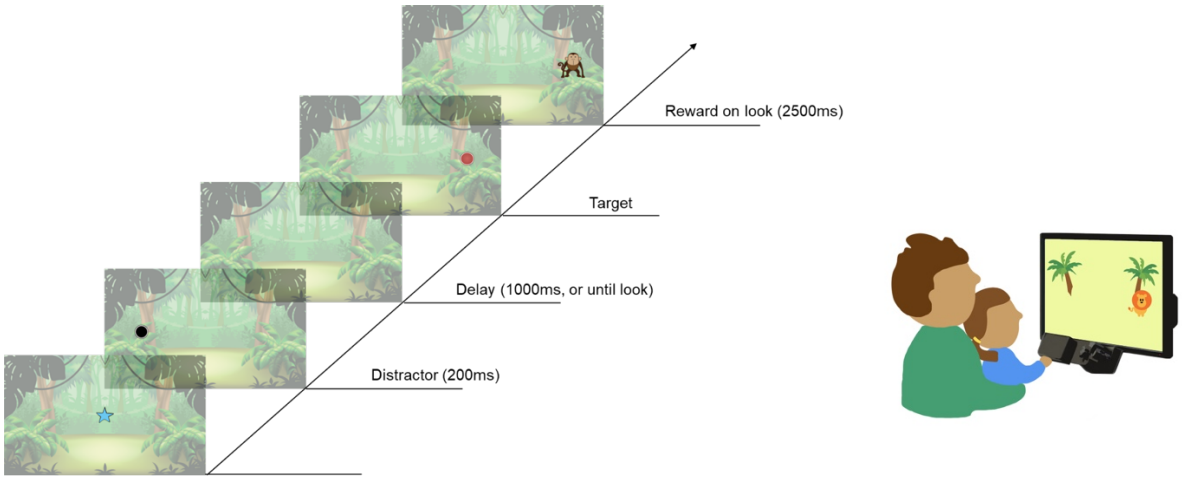

Figure 6: Schematic of the procedure for the Anti-saccade eye tracking task. Participants were rewarded for looking at the red dot and should learn to ignore the black distractor dot appearing first on the opposite side of the screen.

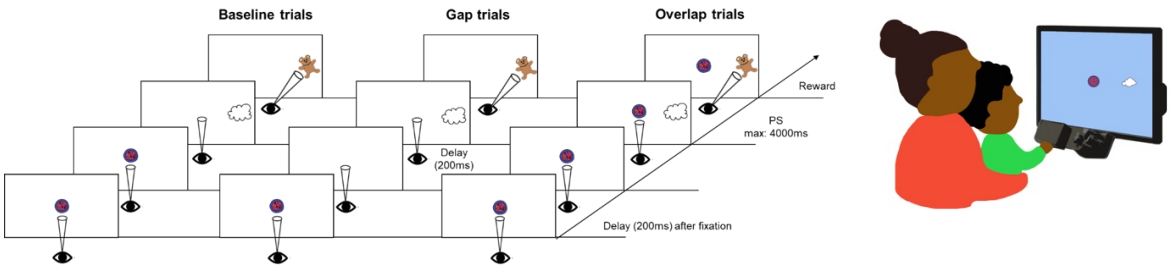

Figure 7: Schematic of the procedure for the gap-overlap eye tracking task. Participants were rewarded for looking at the peripheral target (the cloud) under three conditions: Baseline - central target disappears when peripheral stimulus (PS) appears, Gap- the PS appears after a 200ms delay from central target disappearance, or Overlap-central target remains present, creating a difficulty in disengaging attention.

After completing the eye-tracking tasks, the Mullen Scale of Early Learning (Mullen, 1995) was administered to look at the child's global development in motor skills, language and perceptual abilities.

Intervention assessments

During the intervention, families in all groups were asked to complete a bi-weekly Bedtime Activity Diary to tell us about the activities their child did in the hour before bed (e.g. screen time, play). The Bedtime Activity Diary also asked about their child's sleep patterns in the last week and caregiver anxiety. Families in the PASTI group also completed a daily Screen Time Questionnaire to examine their child's use of screens in the hour before bed.

Debrief assessments

At the end of the trial, caregivers in the PASTI and Bedtime Box group were asked to complete an online Debrief Questionnaire to tell us about their experiences of taking part in the trial. A random subsample of families in the PASTI group were also invited to take part in a semi-structured debrief interview to gather in-depth information about families views and experiences related to the feasibility of the trial. The interviews took place on Teams or over the phone. For the full data collection timeline see Figure 8.

Figure 8: Full data collection timeline. Note: The dotted lines represented activities that only the PASTI group completed.

Timeline	Baseline (Pre-weeks 1 & 2)		Intervention (Weeks 1 to 5)					Follow up (Weeks 6 & 7)		
	Week 1	Week 2	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 7+
Interventions										
PASTI Intervention group			X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X	
Bedtime Box Comparison Group			X ———	X ———	X ———	X ———	X ———	X ———	X	
Control Group			X ———	X ———	X ———	X ———	X ———	X ———	X	
Home Assessments (all groups)										
Questionnaires (e.g., BISQ, ECBQ)	X							X		
Sleep Actigraphy Watch	X ———	X						X ———	X	
Sleep Dairy	X ———	X						X ———	X	
Lab Assessments (all groups)										
Visual Search Task		X							X	
Antisaccade Task		X							X	
Gap-Overlap Task		X							X	
Mullen Scales of Early Learning		X							X	
Intervention Assessments										
Daily Screen Time Questionnaire (PASTI group only)			X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X - - - - - - - -	X	
Bedtime Activity Diary (all groups)	X ———	X	X ———	X ———	X ———	X ———	X ———	X ———	X	
Parent Debrief Questionnaire (PASTI and Bedtime Box groups only)										X

Data analysis

All data analyses were performed by the junior trial statistician (PC) under the supervision of the senior trial statistician (BC). All analyses followed a pre-registered Statistical Analysis Plan that was prepared and finalised by blinded staff members prior to follow-up data collection completion. All analyses were performed on an *intention-to-treat basis*, which means that all families randomised to a group were included in the analysis regardless of whether they adhered to the trial.

Findings

Recruitment Feasibility

A total of 427 families signed up for the trial from a variety of sources (see Figure 9).

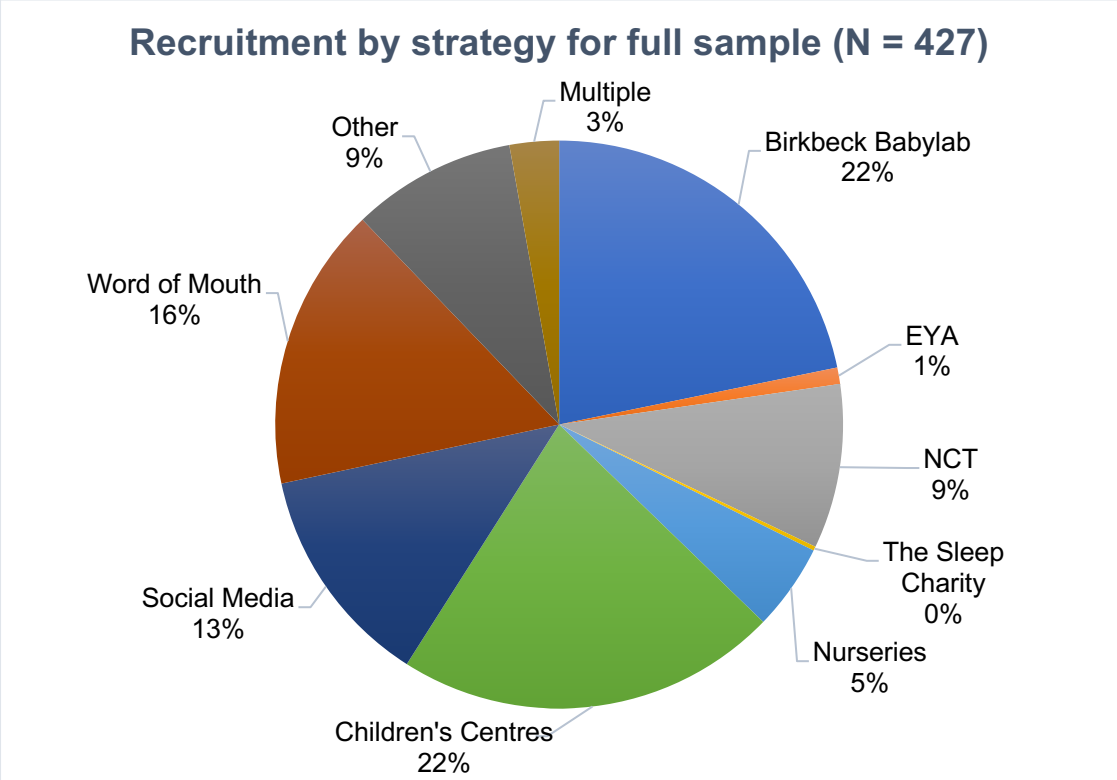

Figure 9: Sources and recruitment method used to recruit all families who signed up for the trial (EYA= Early Years Alliance social media and mailing lists; NCT = National Childbirth Trust social media and mailing lists).

165 families were eligible and 164 were invited to take part. Of the 262 (61%) ineligible families, most of these families were excluded for not having enough reported screen time in the hour before bed (249). Across the full pre-screen sample (N=427), toddlers had screen time in the hour before bed on average 2.89 days in a week (range 0-7 days; see Figure 10). On these days, caregivers reported that toddlers had an average of 12 minutes and 57

seconds of screen time in the hour before bed. Toddlers who met our inclusion criteria had at least 10 minutes of screen time in the hour before bed on 3 days a week.

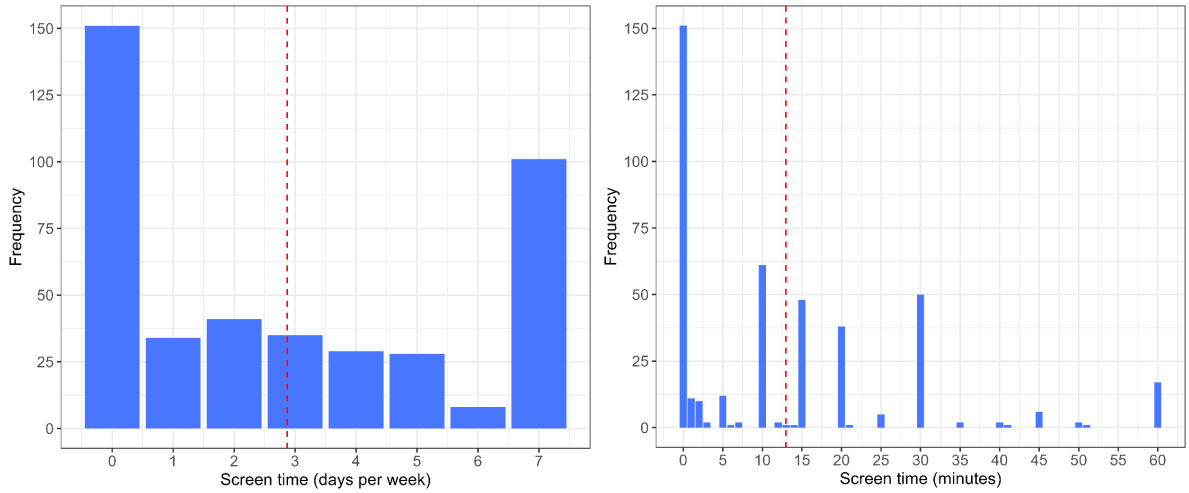

Figure 10: Pre-bed screen time for full pre-screen sample (N=427). Left - Frequency of families reporting average days per week their toddler has screen time in the hour before bed. Right- Average minutes of pre-bed screen time. Dotted red lines denote mean.

To assess the socioeconomic representativeness of our sample we assessed the Index of Multiple Deprivation based on family postcodes (1 = most socially disadvantaged, 5 = least socially disadvantaged). We managed to recruit and randomise families across the full range of socioeconomic status (see Figure 11). Across our pre-screen, eligible and randomised samples, we found that 46%-49% of our families were from the two most disadvantaged socioeconomic groups.

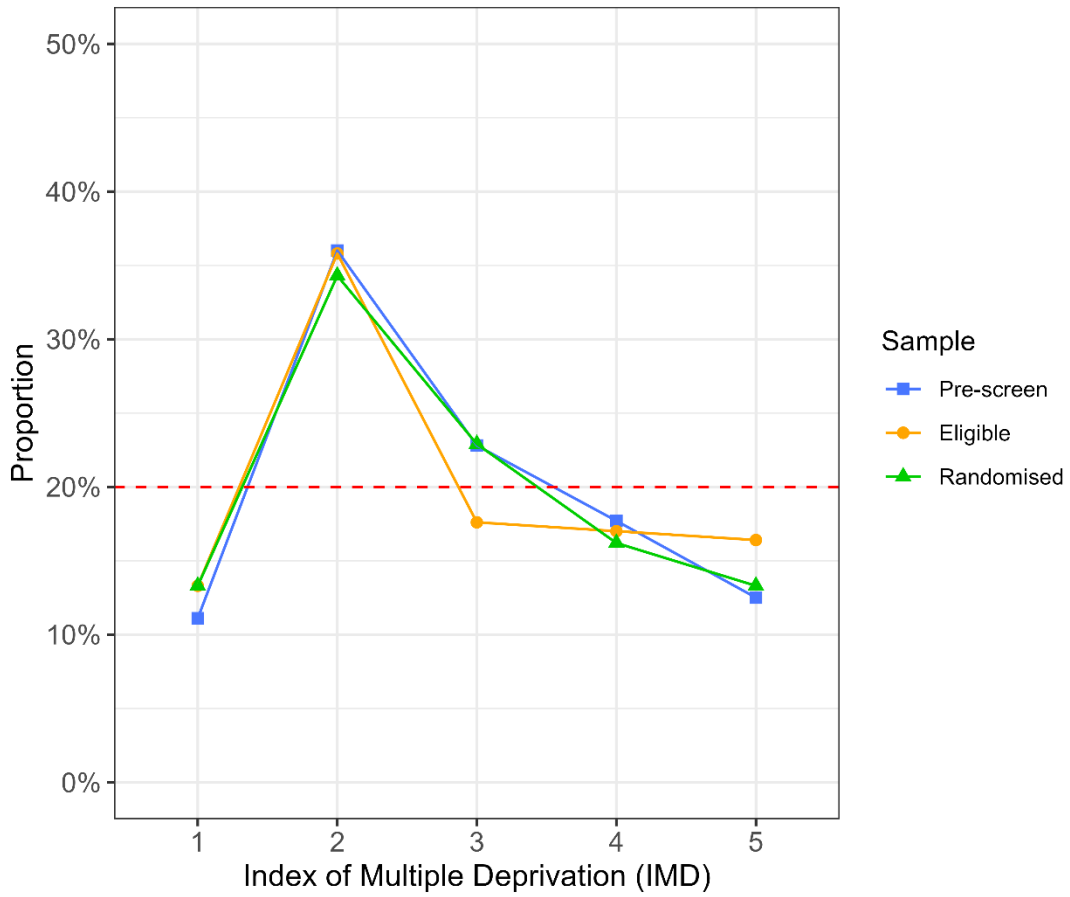

Figure 11: Proportion of families across the range of Index of Multiple Deprivation (1 = most social disadvantage, 5 = least social disadvantage) in our pre-screen (n = 427, n = 2 missing), eligible (n = 165) and randomised (n = 105) samples. The red line indicates chance of being in each quintile.

Of the 164 families invited to take part in our trial, 124 consented to take part in the 7-week intervention. One family was excluded due to having prior knowledge about the full purpose of the trial. 105 families were randomised into either PASTI, Bedtime Box or No Intervention groups (see our CONSORT diagram in Figure 12 for full details below).

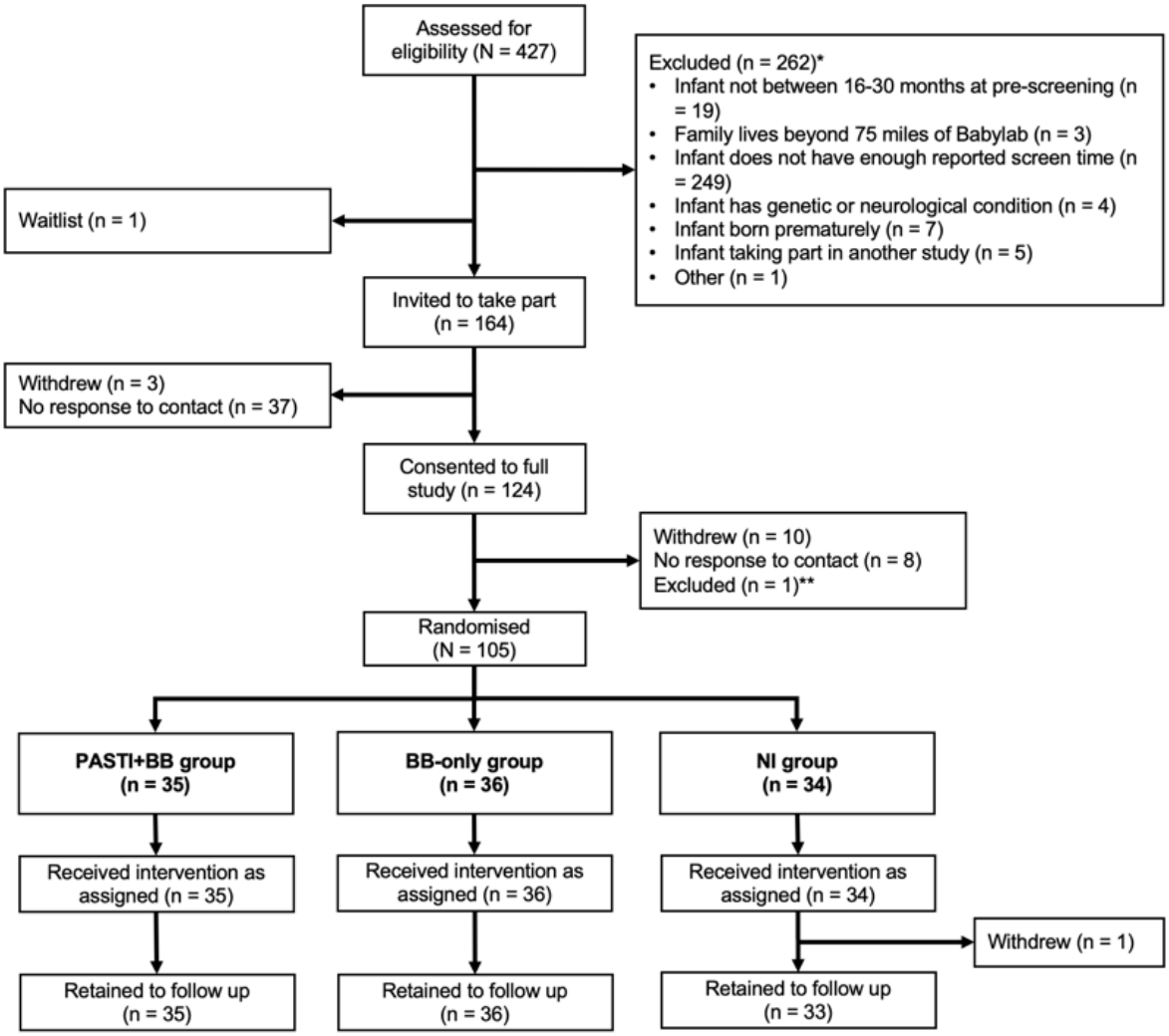

Figure 12: CONSORT diagram

Parent and child demographics for randomised sample

In our randomised sample, 57% of toddlers were male and we managed to recruit an ethnically diverse sample, with 39% of our toddlers from non-white ethnic backgrounds. This mirrors the most recent estimates from the Office of National Statistic reporting that 42% of people in London are from white ethnic backgrounds (ONS, 2019). This shows that the families in our study are representative of the wider Central/Greater London population in terms of ethnicity, which is often underrepresented in developmental research (Rowley & Camacho, 2015). See Appendix A (Table 3) for full demographic information.

Feasibility outcomes

Traffic light metrics of feasibility success are shown in Table 1. The trial met all the 'green light' feasibility metrics, suggesting that a full trial is feasible without modifications to the current design. See the section '

Quantitative experiences of the trial' for further insights about the trial feasibility and subjective experiences of taking part.

Table 1: Trial feasibility traffic light metrics: Red= a full trial using the current design may not be feasible, Amber = a full trial may be feasible, but that the protocol should be modified or monitored closely; Green = a full trial is feasible with the current design.

Metric	Result (95% CI)	Red	Amber	Green
Randomisation (Number of participants randomised overall)	105 randomised	≤ 73	74 to 104	≥105
PASTI daily questionnaire completion (% of participants randomised to PASTI and retained to lab follow-up that complete ≥ 60% of daily screen time questionnaires)	31/35 is 89% (CI: 73% to 97%)	< 65%	65% to 79%	≥80%
PASTI adherence to screen time removal (week 1 – week 6) (% of participants randomised to PASTI that report no screen time on ≥ 60% of daily screen time questionnaires completed)	33/35 is 94% (CI: 81% to 99%)	< 50%	50% to 69%	≥70%
PASTI debrief questionnaire completion (% of participants randomised to PASTI that compete the debrief questionnaire)	33/35 is 94% (CI: 81% to 99%)	< 70%	70% to 74%	≥75%
Retention (% of randomised participants attending follow up Lab visit)	104/105 is 99% (CI: 95% to 99.9%)	< 65%	65% to 74%	≥75%

Preliminary efficacy effects

The secondary aim of this pilot and feasibility trial was to examine the preliminary efficacy of PASTI on outcomes. This analysis allows us to estimate effect sizes that will help us power a future large-scale confirmatory trial. To examine the preliminary effects, linear models were run for each continuous screen time, sleep and attention outcome predicted by intervention group (PASTI, Bedtime Box, No Intervention), whilst controlling for the baseline measure of the outcome and minimisation factors (age, sex and IMD, as a proxy of SES). Adjusted mean

differences for comparisons between PASTI and Bedtime Box, and PASTI and No Intervention are reported in Table 2 and standardised effect sizes for these differences are reported in the forest plots in Figure 13 and Figure 14. Effect sizes are reported as Cohen's *d*, where an effect size of 0.2 indicates a small difference, 0.5 indicates a medium difference and 0.8 indicates a large difference between two mean differences. Full descriptive statistics for the efficacy metrics can be found in Appendix B (Table 4).

Table 2: Adjusted mean differences for PASTI compared to the other groups for follow-up outcomes. Notes. BISQ-R = Brief Infant Sleep Questionnaire - Revised, VST = Visual Search Task, AT = Anti-saccade Task, GT = Gap-Overlap Task, ECBQ = Early Childhood Behaviour Questionnaire, RT = Reaction Times.

Efficacy outcome		**Adjusted mean difference (95% CI)**	
	N	**PASTI vs Bedtime Box**	**PASTI vs No Intervention**
Screen time			
Average screen use in hour before bed (minutes)	75	-9.00 (-14.28 , -3.71)	-13.33 (-18.34 , -8.31)
Sleep			
Average total night-time sleep duration (minutes)	77	-0.96 (-20.45 , 18.53)	2.38 (-16.57 , 21.33)
Average total day-time sleep duration (minutes)	57	-2.30 (-22 , 17.39)	-13.77 (-33.54 , 5.99)
Average frequency of night awakenings	77	-0.23 (-0.53 , 0.07)	-0.21 (-0.50 , 0.09)
Average sleep efficiency (%)	77	1.40 (0.42 , 2.38)	0.68 (-0.27 , 1.63)
BISQ-R sleep onset latency (minutes)	102	0.99 (-9.03 , 11.01)	0.09 (-10.24 , 10.41)
Attention			
VST single search saccadic RT	100	52.2 (-152.38 , 256.77)	59.29 (-150.39 , 268.96)
AT prosaccade saccadic RT (pre-switch)	85	-2.05 (-21.99 , 17.89)	-0.43 (-21.1 , 20.25)
AT proportion of antisaccades (pre-switch)	90	4.84 (-7.58 , 17.25)	-1.24 (-13.78 , 11.3)
GT baseline saccadic RT	78	11.83 (-18.42 , 42.08)	-7.95 (-38.4 , 22.5)
GT disengagement saccadic RT	78	20.69 (-22.67 , 64.04)	21.88 (-21.53 , 65.29)
ECBQ Short Form effortful control	102	-0.21 (-0.39 , -0.03)	0.08 (-0.11 , 0.27)
ECBQ Short Form inhibitory control	102	-0.55 (-0.88 , -0.22)	-0.17 (-0.51 , 0.17)

Screen time

We observed a clear reduction in parent-reported screen time in the hour before bed in the PASTI group. On average, caregivers in the PASTI group reported that their toddler had 13 minutes less screen time in the hour before bed compared to the No Intervention group (*d* = -

0.96 [95% CI: -1.32 to -0.60]) and 9 minutes less screen time in the hour before bed compared to the Bedtime Box group (Cohen's *d* = -0.65 [95% CI: -1.03 to -0.27]).

Sleep

Participants in the PASTI group had a shorter average day-time sleep duration (aMD=-13.77; *d*=-.30 [-.74, .13]), fewer night awakenings (aMD=-.21; *d*=-.28 [-.67, .12]), and increased sleep efficiency (aMD=.68; *d*=.27 [-.11, .66]) compared to No Intervention group. The size of these effects was small-to-moderate, although confidence intervals spanned zero. Compared to the Bedtime Box group, participants in the PASTI group had fewer night awakenings (aMD=-.23; *d*=-.31 [-.71, .10]) with a clearer difference emerging for increased sleep efficiency (aMD=1.40; *d*=.56 [.17, .96]). Specifically, toddlers in the PASTI group had 1.4% better sleep efficiency than the Bedtime Box group.

There was no indication of an effect of PASTI on total night-time sleep duration compared to either the No Intervention group (*d* = 0.05 [-0.35, 0.45]) or Bedtime Box (*d* = -0.02 [-0.43, 0.39]). Parent-reported sleep onset latency in the PASTI group also showed no difference compared to No Intervention (*d* = -0.00 [-0.44, 0.44]), or the Bedtime Box group (*d* = -0.04 [-0.47, 0.38]).

Attention

There was no clear difference between PASTI and No Intervention groups for eye-tracking or parent-report attention measures (see Figure 13). Compared to Bedtime Box, PASTI participants showed no difference on eye-tracking attention measures but a clear difference on parent-reported effortful control (aMD=-.21; *d*=-.40 [-.75, -.05]) and inhibitory control (aMD=-.55; *d*=-.48 [-.77, -.19]), due to an increase in BB-only scores.

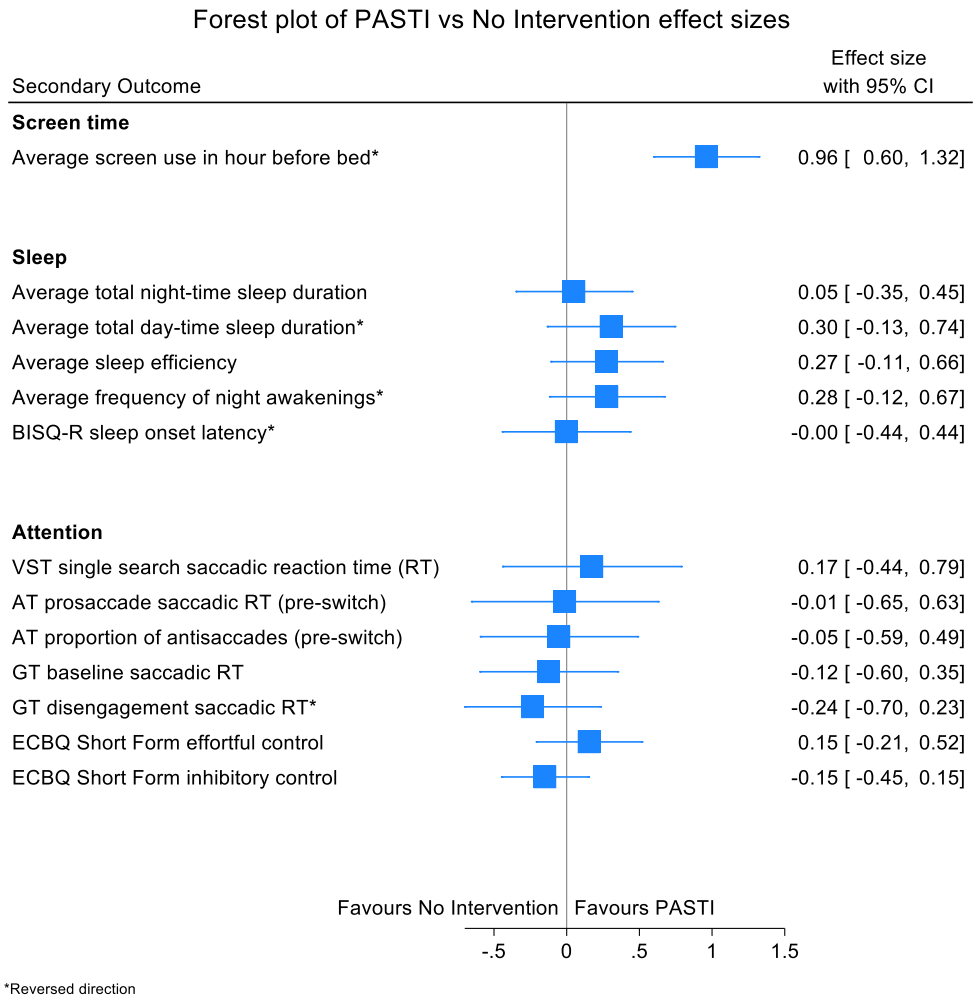

*Figure 13: Forest plots for PASTI vs. No Intervention effect sizes across all outcome measures. Positive effect sizes favour PASTI. Negative effect sizes favour No Intervention. Effect sizes denote Cohen's d. *Denotes outcome measures for which the effect size was reversed in the plot as a lower value was better. The original direction of these reversed effect sizes is reported in the text.*

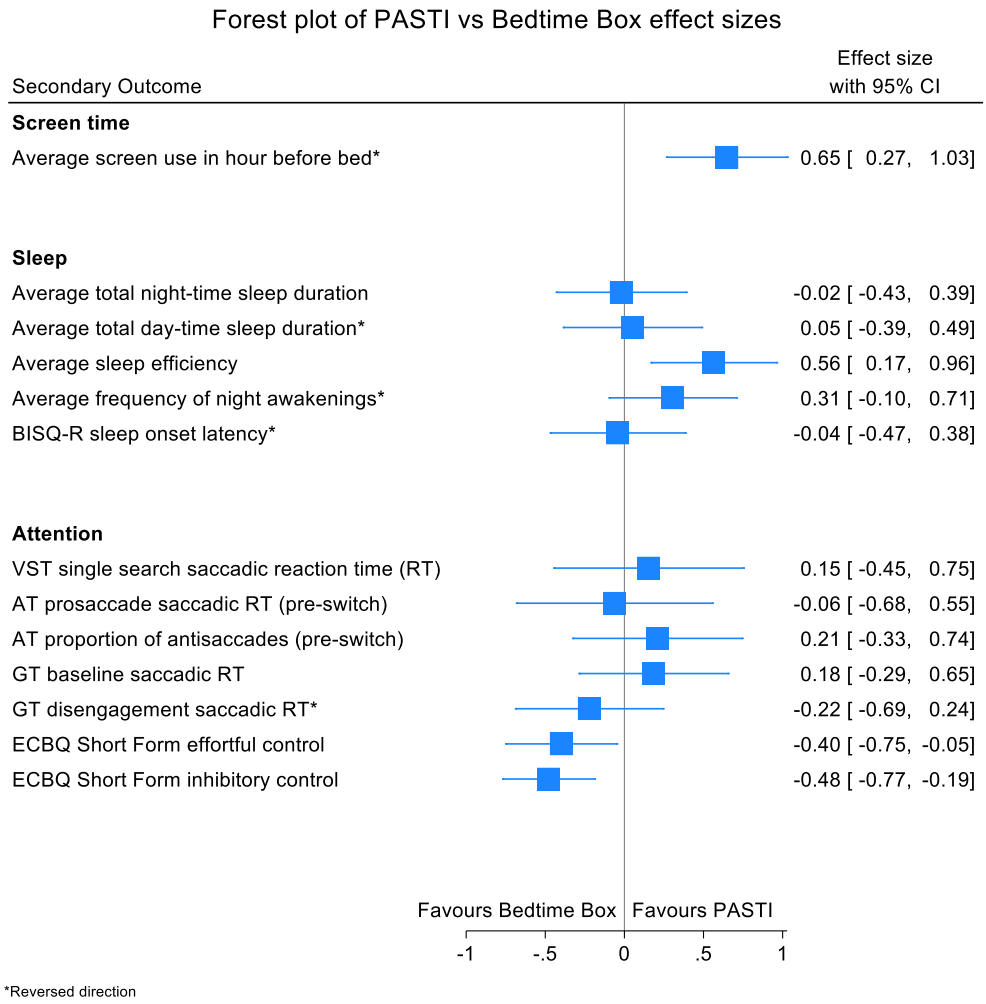

*Figure 14: Forest plots of PASTI vs. Bedtime Box effect sizes across all outcome measures. Positive effect sizes favour PASTI. Negative effect sizes favour Bedtime Box. Effect sizes denote Cohen's d. *Denotes outcome measures for which the effect size was reversed as a lower value was better. The original direction of these reversed effect sizes is reported in the text.*

Quantitative experiences of the trial

Completion rates for the debrief surveys in the PASTI and Bedtime Box groups were 94% (33/35) and 92% (33/36), respectively. Full results of the debrief surveys can be found in Appendices C-F. In total, 85% of families in PASTI found it between 'somewhat' to 'very easy' to remove screen time from their toddler in the hour before bed (see Appendix C, Table 5). The most common challenge reported by caregivers (n = 11) was being unable to avoid their child seeing another family member's screen. Furthermore, 73% of PASTI families agreed or strongly agreed that they would continue to help their child avoid screen time in the hour before bed.

The Family Bedtime Box was well received by families in the PASTI and Bedtime Box group, with 79% of PASTI families and 91% of Bedtime Box families agreeing or strongly agreeing that their child enjoyed using the box in the hour before bed (Appendix D, Table 6). In addition,

94% of PASTI families and 94% of Bedtime Box families reported using the Family Bedtime Box more than a few days in the week, as advised by our team. Overall, 97% of PASTI families and 94% of Bedtime Box families agreed/strongly agreed to feeling supported during the trial.

The vast majority of families in the trial agreed that the trial home assessments were acceptable (Appendix E, Table 7). 85% of PASTI families and 82% of Bedtime Box families agreed or strongly agreed that it was easy to complete the questionnaires about their child's sleep, behaviour and general development. Furthermore, the majority of PASTI and Bedtime Box families agreed or strongly agreed that their child was happy to wear the Motion Watch during the day (PASTI: 70%, Bedtime Box: 79%) and at night (PASTI: 85%, Bedtime Box: 91%). With regards to the sleep diary, 85% of the PASTI caregivers and 88% of Bedtime Box caregivers were able to complete the sleep diary on most/all days.

Finally, the majority of families 'agreed' or 'strongly agreed' that their trial participation had been beneficial for them (79% PASTI and 100% Bedtime Box) and their child (82% PASTI and 91% Bedtime Box; see Appendix F, Table 8).

Qualitative experiences of the trial

A random subsample of families in the PASTI group (n = 17 out of 35) took part in a semi-structured interview about their experiences of taking part in the trial. Interviews were transcribed and coded for emerging themes. Preliminary insights suggest three initial themes including 1) *Feasibility of bedtime routine changes*; 2) *Engaging with the intervention assessments*; and 3) *Consequences of screen removal*.

Theme 1: Feasibility of bedtime routine changes.

Ease of removing screen time. Families mentioned that it was relatively easy to remove screen time in the hour before bed: 'See, during the trial we found it extremely easy' [CG9], despite initially feeling like it was going to be challenging: 'So I anticipated it was gonna be really hard, but it actually, when I came to it, it was so much easier than I had brought it up in my head' [CG15]. Caregivers also discussed that their child adapted to the change in screen time quite quickly: 'he adapted very well to having screen time removed. Um, he usually he was he he likes to watch in the night garden. But he was very he he he did, it didn't really bother him' [CG5].

Some families found it challenging to remove screen time when their child was unwell or had a particularly bad day: 'So when she was ill, it was quite tricky [CG3]'; 'I think maybe one or two occasions where he did have it because he was really upset…on days where…he'd had a difficult day or he was overtired or something,…Yeah, one or two times it was very difficult,

but most of the, most of the time it was fine.' [CG1]. This was often due to a disruption in their routine. Families reported that using other activities in place of screen time was helpful: 'Wasn't too bad because we just had to distract him with other thing' [CG1].

Challenges for the wider family. Many families noted that removing screen time in the hour before bed was often more challenging for other family members: 'it was more of a big deal for his brother not to have screen time before bed because he would be the one that would fall asleep with the TV on' [CG6]; 'So actually surprisingly (laughs) there was more push back from the older members of the family, who should know better than the ones from the 2 year old. So yeah, that was probably the trickiest thing…' [CG14]. Some families discussed the challenges around enforcing no screen time when only one parent was at home: 'if my husband's out and I'm single parenting a bit and it's a bit crazy. It's kind of like, OK, you watch TV for half an hour' [CG4] or when their child was staying with a relative: 'when she will go to her grandparent (.) um and it was harder to control or harder to manage. But when she was with us as parents, it was easy to easy to do' [CG8].

Usefulness of the bedtime box. Families found that the bedtime box was a helpful tool for replacing screen time: 'It give her something else to sort of do than watch the TV' [CG16]; 'Yeah, the physical toys were good because then we could use them as an alternative to watching screens' [CG3]. Some caregivers thought it would be particularly good for those who have busy lifestyles: 'I do think they they're very good. And especially like for, for mums that don't like who have busy lifestyles and don't want and you know they can't have a good bedtime routine with with their kids' [CG5]. Some families felt that the activity cards gave them 'really good starting points' [CG6] and useful ideas that were easy to access: '…it was useful. It was nice to have some, some more ideas, you know, instead of just going online and researching' [CG2]. The activities also inspired families to come up with new ideas: 'From the cards they gave us really good starting points for them. Kind of either doing a new activity, a new game, a new kind of trying something new and then also like evolving into other games' [CG15]. Some families acknowledged that the bedtime box was more useful at the start of the trial: 'I used it when I was running out of ideas and definitely in the early stages, but not so much towards the end of the- the trial' [CG14] and that they were also able to use their own toys: 'Yeah, sometimes we would use our own toys. That it would retain like the novelty factor' [CG9]. Although the majority of families were able to use the activity cards in the bedtime box, some found that the cards were not *always age-appropriate* for their child: 'So we didn't use the cards the hour before bed, but we did try and use a few of the activities here and there, but she's- she was a little bit young to get them' [CG17].

Theme 2: Engaging with the intervention assessments.

Importance of delivery. Families emphasised the helpfulness and accessibility of having trial assessments (e.g. questionnaires) and reminders delivered to them via text message: ‘Like I definitely found the text messages like so simple I didn't have to like log into anything it like. They popped up on my phone and it was like really quick to read, so it didn't like take up any time and kind of like going to find information I felt like it's very accessible’ [CG15], as opposed to over email: ‘I think it was helpful that it came via text rather than via e-mail [CG11]’. Text messages were often seen as key to reminding parents to fill in the assessments: ‘Yeah, yeah, the text messages reminding me to actually fill- fill out questionnaires were really useful’ [CG17]. Families had mixed opinions on the frequency of the text messages, with some suggesting that the frequency provided helpful reminders: ‘The frequency I think it was good because it kept reminding me of it. I think if you had it any less, it would be quite easy to think “Ohh” you know it's-. I don't know. It would be easier for it to drop off’ [CG11]; while others found it more challenging: ‘At times I felt like I was a bit panicky because there was a - there seemed to be quite a few messages coming in quite regularly, but obviously that's hit and miss anyway, because it just depends on how busy I am’ [CG13].

Child’s reactions to the Motion Watch. While some families mentioned that their child enjoyed wearing the motion watch: ‘She loved it. She didn't want to take it off (laughs). Like, I don't know, she was a superhero or something?’ [CG7], others spoke about their child not paying it much attention to it: ‘she didn't really- she didn't pay that much attention to it once it was on’ [CG10]. Occasionally, families reported that their child would take the watch off, however, in the majority of cases the caregiver was able to put it back on: ‘she was fine with the watch on the- or the tracker on her foot. She was quite happy with that. I think a couple of times, she took it off, but only for short periods. So on the whole, she's quite happy that that’ [CG3]. This was often due to the child not understanding why they were wearing the watch: ‘She was pretty good. Just every now and then she would be like touching it or wanting it to to remove it. Or probably she wouldn't understand like why? Yeah, but no, it was fine…’ (CG2); ‘The first time round he was getting he, he didn't understand what the watch was for, so he kept taking it off and then he lost it at one stage…But the second time round he left it on the whole time’ [CG5].

Theme 3: Consequences of screen removal.

More time together. Families discussed that the removal of screen time in the hour before bed helped them to spend more time together in the evening: ‘It is nice to kind of spend a bit more time with the kids in the evening rather than just having them sort of filed in front of the telly’

[CG4]; ‘I think the benefit was spending a bit more like family time together and that hour before bed’ [CG12] and be more present with their child: ‘Because it just made me be a bit more present, like, proactive with him’ [CG1]. Families also mentioned that the intervention fostered more interactions: ‘it kind of forced us to interact more as a family and put all the screen devices away, you know, and just like make a big deal of that being the end of the night family time thing as part of the routine rather than everybody just kind of do their own thing’ [CG6] and engagement amongst the whole family: ‘I think we- we got to talk a lot more and collectively as a family we stopped screen time and to be honest, we're still doing that now’ [CG13].

Child developmental changes. Some families reported seeing improvements in their child’s sleep: ‘she was going through a particularly difficult phase of sleeping then, where she just wake up quite a lot during the night. So, like, we noticed that actually she started to sleep a bit better’ [CG17], while others mentioned that they did not notice any changes: ‘So I don't know if that has impacted her sleep or not’ [CG8]. Other families mentioned seeing changes in their child’s temperament: ‘But um I think his state of being was a lot calmer. He wasn't kind of straight out of the car off the phone and then, you know, you know hyper or, you know, agitated and then put him straight into bed. He was a lot calmer. I think it just gives some time to regulate a little bit’ [CG12]. This was thought to be due to other family members slowing down around bedtime: ‘I think kind of thinking about using that last hour to kind of be like as a time for like connection or winding down or do something together I think helps us as parents think about stopping and slowing down. And I think that also then helps [her], because then everything feels a lot calmer, like going into the bath going into bed um going into bed. And then that helps her sleep better’ [CG11].

Greater awareness of screens. As a consequence of taking part in the trial, caregivers reported an increased awareness of screens being on at bedtime in the family home: ‘I think it was a positive thing because without realising I I never noticed that the TV would just kind of be on in the background so often’ [CG6]. One family also mentioned now noticing the impact that screens had on their child: ‘So I mean, it just it just in terms of being aware of screen and just sort of the impact it has on kids. I'm a lot more aware of it. So things like the more interactive things that they-, she just completely zones out’ [CG14]. This greater awareness led to families being more conscious about the hour before bed and what their child is doing during this time: ‘Almost having that like time in my head that was like the hour before bed um made me a bit more mindful about like what we would- what we were doing in that hour’ [CG11]. Families were also more present during the time they spent together: ‘I think it just improved sort of the family time and actually made me stop and concentrate on them rather than doing all the other household stuff that you have to do alongside having family’ [CG10].

This increased awareness led many families to continue with removing screens at bedtime: 'I would say an hour before bed. She still doesn't have any screen time' [CG7]; 'Definitely I'm aware of the screen time. We've definitely cut down on screen time before bed' [CG15]; 'We just kind of made a new rule that there's no TV after bedtime um:: and that that's kind of stuck in the house' [CG4].

Project conclusions and next steps

Reflecting on the findings of our study we are confident that PASTI is feasible and acceptable to use with families who have a 17- to 31-month-old child, including diverse families across our range of IMD quintiles. There are several findings from this project that will inform the next steps when thinking about planning a large full-scale randomised control trial.

Summary of key findings

Overall, we were able to successfully deliver a Parent-Administered Screen Time Intervention (PASTI) to families with a 16- to 30-month-old toddler with pre-existing parent-reported screen time in the hour before bed. Our key findings are:

1. **The PASTI trial was highly feasible for families:** we met our target of randomising 105 families, retained 104 families to trial completion, and adherence to the PASTI intervention was excellent (94% of families reporting that their toddler did not have any screen time on ≥ 60% of days).
2. **PASTI was successful at reducing screen time:** PASTI families reported a reduction of their toddler's screen time in the hour before bed by the end of the trial: 13 minutes less screen time than the No Intervention group and 9 minutes less screen time than the Bedtime Box group.
3. **PASTI showed no improvements in toddler attention:** There was no clear impact of PASTI on objective eye-tracking measures compared to both Bedtime Box and No Intervention or parent-report measures of attention when compared to the No Intervention group. We found that Bedtime Box families reported that their toddler had greater parent-reported effortful control and inhibitory control, compared to PASTI families. Replication of this finding and further exploration is required.
4. **PASTI showed preliminary improvement in the quality of toddler sleep:** Toddlers in PASTI had shorter average day-time sleep duration, fewer night awakenings and higher sleep efficiency compared to the No Intervention group after the intervention period, but the difference between these groups is small and needs replication. A clearer improvement emerged when compared to families in the Bedtime Box group, as toddlers in PASTI had higher sleep efficiency and fewer night awakenings. Although our modest sample size may

have limited us finding a clear difference between our groups, these results suggest a small improvement in toddlers' sleep as a consequence of PASTI. These findings support a wealth of correlational evidence that shows a link between screen use and poor sleep (Cheung et al., 2017; Hiltunen et al., 2021).

Next steps

In order to plan the next steps for PASTI, we held a **Future's Workshop** with our Early Years Stakeholder Panel (representatives from NCT, EYA and the Sleep Charity), Children's Centre managers and a parent who took part in our trial. Further insights about the feasibility of national roll-out were sought during two presentations (October 12th, 2023 and April 30th, 2024) to the National Quality Improvement Network (NQIN), a network includes representatives from Local Authorities and selected national early years organisations hosted by the National Children's Bureau (NCB). NQIN is a network of Early Years policy makers who set the standards and practices for early-years practice across the UK.

Across a series of discussions and activities the workshops produced important insights into the PSTI findings, the full-trial design and future roll-out in early-years practice.

Futures Workshop: Reflections on Findings

The early-years experts were impressed by the success of the trial, the rigor with which it was conducted -especially in light of the challenges we faced with recruitment/in-person testing in the aftermath of the pandemic- and the positive effects PASTI had on toddler sleep. Half of the Futures panel (members of the EYSP) were involved in the initial co-creation of the intervention materials and they were incredibly proud to see how well the materials had been received by families. The excellent adherence families had shown to the intervention, retention throughout the trial and the lack of adverse events and problems encountered by families was testament to the efforts put in by the PASTI team and EYSP to design the intervention in a way that accommodated the realities of toddler bedtimes and the pressures on their caregivers.

The importance of providing the Bedtime Box and activity cards as a way for parents to replace screen time with healthy pre-bed activities was commented on by the Futures panel: "the pre bedtime activities, we chose them to calm brain wave patterns. So if they are going to bed with calmer brains, we know if you got to sleep in a calmer environment you sleep better at night" [Sleep Practitioner]; "So I think it is definitely a combination of no screens but also …. the time they have with their parents [created by the Bedtime Box]" [PASTI Parent].

Both the Futures panel and NQIN audience were fully in support of a full confirmatory trial of PASTI and future introduction into early-years practice.

Futures Workshop: Practicalities of scaling up for a full trial and future national roll out

The challenges of scaling up the PASTI protocol (target N = 105 families within Greater London) to a full confirmatory trial (N~1760 pre-screen, N=420 randomised sample nationwide) and future roll-out in early-years practice were discussed in length.

Our experts believed that PASTI would be of interest to Children's Centre staff due to the emphasis on sleep -a common focus of their work- but that allocating extra time to deliver the intervention would be difficult given how stretched current resources are. Family Hubs were also discussed as another possible route for recruiting families and administering PASTI (https://familyhubsnetwork.com). Family Hubs are local support centres where families with children can access a broad and integrated range of help. However, the local variation in how hubs work in their communities and the staff available may create challenges for maintaining consistency in the PASTI trial protocol or future implementation of the intervention.

The possibility of switching to delivering PASTI remotely, providing the resources online to parents without a local in-person contact was discussed. All Futures panel members agreed that this would not be ideal as knowing there was a person helping parents through the trial helped with motivation and support. Similarly, the daily text messages were seen as a positive: "that constant communication but not bombarding…helps to kind of build those relationships to help with retention" [PASTI Parent]. Alternative forms of support, such as peer groups, were discussed. If randomisation by local group were possible, peer groups may offer support without requiring a trained expert but run the risk of introducing local variation in how the intervention is administered.

All experts agreed that the pros of dropping the lab visit outweighed the cons. Whilst some parents may have enjoyed the visit, "For some of the families, that was a nightmare for them. Bringing a child up into London…so may be a barrier." [PASTI parent].

One final point members of both the Futures and NQIN workshops were keen to emphasise was the need for future applications of PASTI to identify the needs of specific family profiles such as those including neurodiverse children and parents, or children with health conditions impacting sleep. Whether PASTI can accommodate these specific profiles or should be avoided by such families' needs to be investigated.

Once the full confirmatory trial of PASTI is successful, future roll-out of the intervention could utilise similar distributions systems as the full trial, although the burden on local administrators and families would be significantly less as there would no longer be a need for randomisation or collecting measures. Experts in implementation science and health economics must be consulted to fully understand the steps to full roll-out and funding required.

Full-trial Considerations and Power

The excellent feasibility findings, qualitative participant insights and approval from the early-years stakeholders all indicate that there is no reason to deviate from the PASTI protocol for the full confirmatory trial. Some minor changes may be required to up-scale the trial and broaden the national reach beyond Greater London (see below), but these will not impact the primary protocol, intervention design or primary efficacy, e.g. objective sleep. Given that the Bedtime Box arm only served as an active control to PASTI in this trial, matching the pre-bed activities so that the independent effect of screen time removal could be assessed and was not intended as a standalone intervention it can be dropped from a future confirmatory trial.

As there was no indication in the pilot efficacy outcomes that PASTI changed any of the objective attention measures and given the complexity of bringing participants to the eye tracking lab, there appears to be motivation to drop the lab visit and the objective eye tracking measures. The absence of a signal does not mean there is no effect as our measures may have failed to capture the relevant aspects of attention or the time period over which they were compared (7-weeks, pre vs post) may have been wrong to capture an effect. However, to increase feasibility of scaling up PASTI we recommend dropping eye tracking measures of attention and relying on parent-report measures until such time that remote low-resource methods for objectively recording attention becomes available, e.g. webcam-based eye tracking.

Based on the PASTI vs. No Intervention pilot effect sizes reported here (see Figure 13), which range from a Cohen's *d* of 0.27 (Sleep Efficiency) to 0.3 (Day-time sleep duration), the sample size required for a full trial to replicate these effects (Cohen's *d* ~0.3) between the two arms (PASTI vs No Intervention) with 80% power, 5% significance and an attrition rate of 20% would require 440 families (220 per arm).

Recommendations

Implications for the **research** community include:

- In support of current pediatric recommendations, removing screen time before toddler bedtime is feasible and shows modest preliminary beneficial effects on sleep.
- No pilot evidence of an effect on objective measures of attention was found. Although an absence of evidence does not indicate evidence of absence. Further investigation is required.
- Pilot effects showing improvement in sleep efficiency and night awakenings in the PASTI group compared to Bedtime Box group suggests a specific causal impact of screen time on sleep, independent from the pre-bed activities screen time may normally displace.
- A future full confirmatory trial is needed to identify the size of the effects on sleep.

Implications for the **policy** community include:

- Our excellent feasibility findings confirm that caregivers are able to adhere to the current recommendations to avoid screen time in the hour before bed for their toddlers when supported to do so via PASTI.
- Our pilot efficacy findings provide the first causal evidence supporting the presumed benefits of avoiding screen time in the hour before bed for toddlers.
- A fully-powered confirmatory RCT of PASTI is required before PASTI is integrated into early-years practice and recommendations.

Implications for the **caregiver practice** include:

- Toddler caregivers should continue following recommendations for good sleep hygiene and avoiding screen time in the hour before bed whilst the full confirmatory RCT of PASTI is conducted.
- The success of our trial lay in working in collaboration with caregivers and early-years experts to ensure their needs and those of their children were represented in the design of PASTI. By allowing flexibility within the intervention and avoiding the negative language often present in the discourse on screen time we believe parents felt empowered to make changes that they believed would benefit their families.

Conclusions

For the first time, we have demonstrated that a parent-administered pre-bed screen time intervention is feasible for families of toddlers and may result in improved toddler sleep. By applying a rigorous pre-registered randomised controlled trial methodology, blinding, randomisation with minimisation of confounding factors (age, sex, socioeconomic status), and objective outcome measures we can have confidence in the findings of this trial and the pilot

evidence that screen time removal may improve sleep. Also, by comparing the Bedtime Box intervention to PASTI (screen removal + bedtime box) we can attribute the difference in sleep outcomes to the screen removal independent of correlated factors, i.e. other pre-bed activities promoted in the Bedtime Box. PASTI is a low-cost, low resource and easy to administer intervention that is inclusive of diverse family profiles and may be feasible to deploy *en masse* within existing UK early-years support services. A fully-powered confirmatory trial is required before full adoption but pilot results are promising and should inform future early-years education policy and parenting practices to ensure the wellbeing and health of present and future generations.

The PASTI pilot and feasibility findings have been accepted for publication. Public dissemination of the findings are embargoed until the day of publication, at which time the trial findings will be disseminated widely via a press release, newsletter to participant families, presentations at our partner organisation's annual general meetings (NCT, EYA and Sleep Charity) and via our project website: https://www.cinelabresearch.com/.

References

Carter B, Rees P, Hale L, Bhattacharjee D, Paradkar MS. Association between portable screen-based media device access or use and sleep outcomes: a systematic review and meta-analysis. JAMA pediatrics. 2016;170(12):1202-8. 10.1001/jamapediatrics.2016.2341

Chang AM, Aeschbach D, Duffy JF, Czeisler CA. Evening use of light-emitting eReaders negatively affects sleep, circadian timing, and next-morning alertness. Proceedings of the National Academy of Sciences. 2015;112(4):1232-7. 10.1073/pnas.1418490112

Cheung CH, Bedford R, Saez De Urabain IR, Karmiloff-Smith A, Smith TJ. Daily touchscreen use in infants and toddlers is associated with reduced sleep and delayed sleep onset. Scientific reports. 2017;7(1):1-7. 10.1038/srep46104

Gangwisch JE, Babiss LA, Malaspina D, Turner BJ, Zammit GK, Posner K. Earlier parental set bedtimes as a protective factor against depression and suicidal ideation. Sleep. 2010;33(1):97-106. 10.1093/sleep/33.1.97

Gentile, D. A., Berch, O. N., Choo, H., Khoo, A., & Walsh, D. A. (2017). Bedroom media: One risk factor for development. *Developmental Psychology*, *53*(12), 2340.

Gradisar M, Wolfson AR, Harvey AG, Hale L, Rosenberg R, Czeisler CA. The sleep and technology use of Americans: findings from the National Sleep Foundation's 2011 Sleep in America poll. Journal of Clinical Sleep Medicine. 2013;9(12):1291-9. 10.5664/jcsm.3272

Hiltunen P, Leppänen MH, Ray C, Määttä S, Vepsäläinen H, Koivusilta L, Sajaniemi N, Erkkola M, Roos E. Relationship between screen time and sleep among Finnish preschool children: results from the DAGIS study. Sleep Medicine. 2021;77:75-81. 10.1016/j.sleep.2020.11.008

Hoyniak CP, Petersen IT, McQuillan ME, Staples AD, Bates JE. Less Efficient Neural Processing Related to Irregular Sleep and Less Sustained Attention in Toddlers. Dev Neuropsychol. 2015;40(3):155-166. 10.1080/87565641.2015.1016162

Lam LT, Lam MK. Sleep Disorders in Early Childhood and the Development of Mental Health Problems in Adolescents: A Systematic Review of Longitudinal and Prospective Studies. Int J Environ Res Public Health. 2021;18(22):11782. Published 2021 Nov 10. doi:10.3390/ijerph182211782

Law EC, Han MX, Lai Z, et al. Associations Between Infant Screen Use, Electroencephalography Markers, and Cognitive Outcomes. JAMA Pediatr. 2023;177(3):311–318. 10.1001/jamapediatrics.2022.5674

Lewis L, Povey R, Rose S, Cowap L, Semper H, Carey A, Bishop J, Clark-Carter D. What behavior change techniques are associated with effective interventions to reduce screen time in 0–5 year olds? A narrative systematic review. Preventive Medicine Reports. 2021;23:101429. 10.1016/j.pmedr.2021.101429

Lillard AS, Peterson J. The immediate impact of different types of television on young children's executive function. Pediatrics. 2011;128(4):644-9. 10.1542/peds.2010-1919

Lin YM, Kuo SY, Chang YK, Lin PC, Lin YK, Lee PH, Lin PH, Chen SR. Effects of parental education on screen time, sleep disturbances, and psychosocial adaptation among Asian preschoolers: a randomized controlled study. Journal of Pediatric Nursing. 2021 Jan 1;56:e27-34. 10.1016/j.pedn.2020.07.003

Martin KB, Bednarz JM, Aromataris EC. Interventions to control children's screen use and their effect on sleep: A systematic review and meta-analysis. Journal of Sleep Research. 2021;30(3):e13130. 10.1111/jsr.13130

Mireku MO, Barker MM, Mutz J, Dumontheil I, Thomas MS, Röösli M, Elliott P, Toledano MB. Night-time screen-based media device use and adolescents' sleep and health-related quality of life. Environment international. 2019;124:66-78. 10.1016/j.envint.2018.11.069

Mullen EM. Mullen scales of early learning. Circle Pines, MN: AGS; 1995.

Nikkelen SW, Valkenburg PM, Huizinga M, Bushman BJ. Media use and ADHD-related behaviors in children and adolescents: A meta-analysis. Developmental psychology. 2014;50(9):2228. 10.1037/a0037318

Ofcom. Children and Parents: Media Use and Attitudes. Ofcom.org.uk. March 2023. Accessed October 2023. https://www.ofcom.org.uk/__data/assets/pdf_file/0027/255852/childrens-media-use-and-attitudes-report-2023.pdf

Portugal AM, Bedford R, Cheung CH, Gliga T, Smith TJ. Saliency-driven visual search performance in toddlers with low–vs high–touch screen use. JAMA pediatrics. 2021a;175(1):96-7. 10.1001/jamapediatrics.2020.2344

Portugal AM, Bedford R, Cheung CH, Mason L, Smith TJ. Longitudinal touchscreen use across early development is associated with faster exogenous and reduced endogenous attention control. Scientific Reports. 2021b;11(1):2205. 10.1038/s41598-021-81775-7

Rowley, S. J., & Camacho, T. C. (2015). Increasing diversity in cognitive developmental research: Issues and solutions. Journal of Cognition and Development, 16(5), 683-692.

Royal College of Paediatrics and Child Health. The Health Impacts of Screen Time – A Guide for Clinicians and Parents. Rcpch.ac.uk. January 2019. Accessed October 2023. https://www.rcpch.ac.uk/resources/health-impacts-screen-time-guide-clinicians-parents

Sadeh A, Hauri PJ, Kripke DF, Lavie P. The role of actigraphy in the evaluation of sleep disorders. Sleep. 1995 Jun 1;18(4):288-302.

Sadeh A. A brief screening questionnaire for infant sleep problems: validation and findings for an Internet sample. Pediatrics. 2004;113(6):e570-7. 10.1542/peds.113.6.e570

Schmidt ME, Haines J, O'brien A, McDonald J, Price S, Sherry B, Taveras EM. Systematic review of effective strategies for reducing screen time among young children. Obesity. 2012;20(7):1338-54. 10.1038/oby.2011.348

Stein MA, Weiss M, Hlavaty L. ADHD treatments, sleep, and sleep problems: complex associations. Neurotherapeutics. 2012;9(3):509-517. 10.1007/s13311-012-0130-0

Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomized controlled trials: a simulation study. *Trials.* 2014;15:1-3. 10.1186/1745-6215-15-264

Wu L, Sun S, He Y, Jiang B. The effect of interventions targeting screen time reduction: a systematic review and meta-analysis. Medicine. 2016;95(27). 10.1097/MD.0000000000004029

Appendices

Appendix A

Table 3: Minimisation factors and demographic information for randomised sample (frequencies; percentages in parentheses).

Minimisation factors and baseline demographics	PASTI (n=35)	Bedtime Box (n=36)	No Intervention (n=34)	Overall (N=105)
Child sex				
Male	20 (57%)	21 (58%)	19 (56%)	60 (57%)
Female	15 (43%)	15 (42%)	15 (44%)	45 (43%)
IMD Quintile				
1 (most deprived)	5 (14%)	4 (11%)	5 (15%)	14 (13%)
2	12 (34%)	13 (36%)	11 (32%)	36 (34%)
3	8 (23%)	8 (22%)	8 (24%)	24 (23%)
4	5 (14%)	6 (17%)	6 (18%)	17 (16%)
5 (least deprived)	5 (14%)	5 (14%)	4 (12%)	14 (13%)
Child age at randomisation				
17-24.4	18 (51%)	18 (50%)	17 (50%)	53 (50%)
24.5-31	17 (49%)	18 (50%)	17 (50%)	52 (50%)
Mean (SD)	23.7 (5.2)	23.5 (4.2)	24.0 (4.6)	23.7 (4.6)
Child ethnicity				
Any White background	22 (63%)	18 (50%)	21 (62%)	61 (58%)
Mixed background	4 (11%)	9 (25%)	5 (15%)	18 (17%)
Asian/South Asian	4 (11%)	2 (6%)	4 (12%)	10 (10%)
Other	5 (14%)	6 (17%)	2 (6%)	13 (12%)
Missing	*0 (0%)*	*1 (3%)*	*2 (6%)*	*3 (3%)*
Does your child have any medical conditions?				
No	32 (91%)	34 (94%)	32 (94%)	98 (93%)
Yes	3 (9%)	2 (6%)	2 (6%)	7 (7%)
Any siblings				
No siblings	18 (51%)	23 (64%)	23 (68%)	64 (61%)
1+ sibling	17 (49%)	13 (36%)	11 (32%)	41 (39%)
Younger siblings				
0	34 (97%)	34 (94%)	31 (91%)	99 (94%)
1	0 (0%)	2 (6%)	3 (9%)	5 (5%)
2	1 (3%)	0 (0%)	0 (0%)	1 (1%)
Older siblings				
0	19 (54%)	25 (69%)	25 (74%)	69 (66%)
1	13 (37%)	7 (19%)	8 (24%)	28 (27%)
2+	3 (9%)	4 (11%)	1 (3%)	8 (8%)
Caregiver age in years				

Mean (SD)	35 (5)	36 (5)	36 (4)	36 (5)
Who is filling out this questionnaire?				
Mother	35 (100%)	34 (94%)	34 (100%)	103 (98%)
Father	0 (0%)	2 (6%)	0 (0%)	2 (2%)
Respondent is sole caregiver				
No	29 (83%)	30 (83%)	30 (88%)	89 (85%)
Yes	6 (17%)	6 (17%)	4 (12%)	16 (15%)
Caregiver ethnicity				
Any White background	24 (69%)	19 (53%)	24 (71%)	67 (64%)
Mixed background	1 (3%)	2 (6%)	3 (9%)	6 (6%)
Asian/South Asian	5 (14%)	7 (19%)	4 (12%)	16 (15%)
Black/African/Caribbean	2 (6%)	2 (6%)	1 (3%)	5 (5%)
Other	3 (9%)	6 (17%)	2 (6%)	11 (10%)
Caregiver highest education				
School leaving qualification or equivalent	2 (6%)	4 (11%)	1 (3%)	7 (7%)
College or equivalent	3 (9%)	5 (14%)	3 (9%)	11 (10%)
University or equivalent	14 (40%)	11 (31%)	16 (47%)	41 (39%)
Post-graduate or equivalent	16 (46%)	15 (42%)	14 (41%)	45 (43%)
Not applicable	0 (0%)	1 (3%)	0 (0%)	1 (1%)
Caregiver speaks fluent English?				
No	0 (0%)	0 (0%)	1 (3%)	1 (1%)
Yes	35 (100%)	36 (100%)	33 (97%)	104 (99%)
Do you live in Greater/Central London?				
No	6 (17%)	0 (0%)	7 (21%)	13 (12%)
Yes	29 (83%)	36 (100%)	27 (79%)	92 (88%)
Completed weeks of pregnancy				
Mean (SD)	39.4 (1.3)	39.5 (1.2)	39.7 (1.3)	39.5 (1.2)

Appendix B

Table 4: Baseline and Follow-up efficacy outcome means (variation; IQR or SD) and sample size for each metric [N].

		Baseline				Follow up			
Efficacy outcomes	**Summary [N available]**	**PASTI (N = 35)**	**Bedtime Box (N = 36)**	**No Intervention (N = 34)**	**Overall (N = 105)**	**PASTI (N = 35)**	**Bedtime Box (N = 36)**	**No Intervention (N = 34)**	**Overall (N = 105)**
Screen use									
Average screen use in hour before bed (minutes)	Median (IQR) [N]	9 (4-24) [29]	18 (9-23) [28]	11 (1-20) [30]	13 (4-23) [87]	0 (0-0) [29]	7 (0-16) [27]	12 (1-21) [31]	4 (0-16) [87]
Sleep									
Average total night-time sleep duration (minutes)	Mean (SD) [N]	606 (49) [31]	606 (54) [32]	601 (39) [32]	604 (48) [95]	596 (55) [27]	595 (51) [27]	590 (37) [27]	594 (48) [81]
Average total day-time sleep duration (minutes)	Mean (SD) [N]	86 (49) [29]	74 (50) [24]	75 (34) [21]	79 (45) [74]	82 (54) [23]	75 (50) [20]	84 (33) [22]	80 (46) [65]
Average frequency of night awakenings	Median (IQR) [N]	1 (0-2) [31]	0 (0-1) [32]	0 (0-1) [32]	0 (0-1) [95]	1 (0-1) [27]	1 (0-1) [27]	1 (0-1) [27]	1 (0-1) [81]
Average sleep efficiency (%)	Median (IQR) [N]	88 (84-90) [31]	88 (87-90) [32]	89 (87-90) [32]	89 (87-90) [95]	88 (86-89) [27]	87 (86-88) [27]	88 (86-89) [27]	87 (86-89) [81]
BISQ-R sleep onset latency (minutes)	Median (IQR) [N]	30 (15-60) [35]	30 (20-60) [36]	30 (15-40) [34]	30 (15-45) [105]	20 (10-45) [34]	25 (15-52) [36]	20 (15-32) [32]	20 (15-45) [102]
Attention									
VST single search saccadic reaction time (ms)	Median (IQR) [N]	1027 (801-1221) [34]	936 (847-1264) [36]	998 (782-1194) [34]	998 (801-1212) [104]	998 (764-1165) [33]	1043 (776-1179) [35]	996 (696-1268) [32]	1009 (746-1177) [100]
AT prosaccade saccadic reaction time (ms)	Mean (SD) [N]	317 (32) [31]	310 (35) [34]	318 (29) [33]	315 (32) [98]	304 (33) [31]	303 (44) [31]	305 (38) [26]	304 (38) [88]
AT proportion of antisaccades (%)	Median (IQR) [N]	20 (0-40) [33]	0 (0-27) [35]	17 (7-38) [33]	12 (0-33) [101]	23 (0-44) [31]	10 (0-40) [31]	20 (0-43) [28]	15 (0-40) [90]
GT baseline saccadic reaction time (ms)	Median (IQR) [N]	340 (286-384) [30]	326 (296-376) [31]	338 (312-369) [32]	335 (299-374) [93]	336 (295-375) [31]	321 (289-353) [27]	332 (308-364) [25]	326 (295-364) [83]
GT disengagement saccadic reaction time (ms)	Mean (SD) [N]	132 (96) [30]	142 (98) [31]	153 (87) [32]	143 (93) [93]	116 (93) [31]	100 (118) [27]	107 (83) [25]	108 (98) [83]

ECBQ Short Form effortful control (1-7)	Mean (SD) [N]	4.7 (0.6) [35]	4.6 (0.5) [36]	4.6 (0.5) [34]	4.6 (0.5) [105]	4.8 (0.7) [34]	4.9 (0.6) [36]	4.6 (0.4) [32]	4.8 (0.6) [102]
ECBQ Short Form inhibitory control (1-7)	Mean (SD) [N]	3.8 (1.2) [35]	3.7 (1.2) [36]	3.8 (1.1) [34]	3.8 (1.1) [105]	3.7 (1.2) [34]	4.2 (1.1) [36]	3.9 (0.7) [32]	3.9 (1.0) [102]

Appendix C

Table 5: Debrief survey responses for the PASTI group

PASTI-only debrief question	Response type	Summary (N=33)
How easy was it to remove screen time for your child in the hour before bed?		
	Very Easy	7 (21%)
	Easy	11 (33%)
	Somewhat Easy	10 (30%)
	Neither Easy nor Difficult	1 (3%)
	Somewhat Difficult	4 (12%)
Challenges experienced during trial		
Tantrums around screentime removal		6
Unable to avoid child seeing another family member's screen		11
Difficult to alter existing bedtime routine		2
Intervention was disruptive to rest of family		6
Disrupted sleep / new sleep issues		1
Increased tantrums in general		2
Difficult to avoid screentime when other caregiver providing care		9
Special occasions/holidays made sticking to intervention difficult		6
Fitting in work commitments around bedtime routine		6
Fitting in household chores around bedtime routine		6
Other		4
None of the above		3
I found the Family Bedtime Box and its contents helpful for replacing screen time in the hour before bed		
	Strongly Agree	10 (30%)
	Agree	15 (45%)
	Somewhat Agree	5 (15%)
	Neither Agree nor Disagree	1 (3%)
	Somewhat Disagree	1 (3%)
	Disagree	1 (3%)
I found it helpful to have the phone/video call with a researcher in the first week of the intervention		
	Strongly Agree	10 (30%)
	Agree	12 (36%)
	Somewhat Agree	6 (18%)
	Neither Agree nor Disagree	4 (12%)
	Not applicable	1 (3%)
During the trial it was easy for me to complete the daily screen time questionnaire		
	Strongly Agree	21 (64%)
	Agree	11 (33%)
	Somewhat Agree	1 (3%)

I will continue to help my child avoid screen time in the hour before bed now that the trial has ended		
	Strongly Agree	16 (48%)
	Agree	8 (24%)
	Somewhat Agree	7 (21%)
	Neither Agree nor Disagree	2 (6%)

Notes. Responses to questions where no answer was given are not displayed in the table.

Appendix D

Table 6: Debrief survey response for PASTI and Bedtime Box groups on the trial support questions

Trial support questions	Response type	PASTI (N=33)	Bedtime Box (N=33)
Overall, my child enjoyed using the Family Bedtime Box			
	Strongly Agree	15 (45%)	19 (58%)
	Agree	11 (33%)	11 (33%)
	Somewhat Agree	5 (15%)	2 (6%)
	Neither Agree nor Disagree	2 (6%)	1 (3%)
My child enjoyed using the toys in the Family Bedtime Box			
	Strongly Agree	15 (45%)	18 (55%)
	Agree	11 (33%)	11 (33%)
	Somewhat Agree	6 (18%)	4 (12%)
	Neither Agree nor Disagree	1 (3%)	0 (0%)
My child enjoyed using the activity cards in the Family Bedtime Box			
	Strongly Agree	4 (12%)	7 (21%)
	Agree	11 (33%)	12 (36%)
	Somewhat Agree	6 (18%)	9 (27%)
	Neither Agree nor Disagree	9 (27%)	3 (9%)
	Somewhat Disagree	1 (3%)	2 (6%)
	Disagree	0 (0%)	0 (0%)
	Strongly Disagree	2 (6%)	0 (0%)
On average during the trial how often did you use the Family Bedtime Box (or similar activities) in the hour before bed?			
	Everyday	5 (15%)	7 (21%)
	Most days of the week (4-6 days)	14 (42%)	19 (58%)
	A few days of the week (2-3 days)	12 (36%)	5 (15%)
	Once a week	1 (3%)	0 (0%)
	Less than once a week	1 (3%)	1 (3%)
	Once a month	0 (0%)	1 (3%)
	Never	0 (0%)	0 (0%)
I found it helpful to receive the weekly Monday check-in messages			
	Strongly Agree	8 (24%)	17 (52%)
	Agree	13 (39%)	8 (24%)
	Somewhat Agree	6 (18%)	4 (12%)
	Neither Agree nor Disagree	6 (18%)	4 (12%)
I found the online Frequently Asked Questions (FAQs) helpful			
	Strongly Agree	4 (12%)	7 (21%)

	Agree	11 (33%)	8 (24%)
	Somewhat Agree	1 (3%)	6 (18%)
	Neither Agree nor Disagree	16 (48%)	12 (36%)
	Somewhat Disagree	0 (0%)	0 (0%)
	Disagree	1 (3%)	0 (0%)
Overall, I felt supported during the trial			
	Strongly Agree	23 (70%)	18 (55%)
	Agree	9 (27%)	13 (39%)
	Somewhat Agree	0 (0%)	2 (6%)
	Neither Agree nor Disagree	1 (3%)	0 (0%)

Notes. Responses to questions where no answer was given are not displayed in the table.

Appendix E

Table 7: Debrief survey response for PASTI and Bedtime Box groups about home assessments.

Home assessment questions	Response type	PASTI (N=33)	Bedtime Box (N=33)
During the home assessments it was easy for me to complete the questionnaires about my child's behaviour, sleep and general development			
	Strongly Agree	16 (48%)	14 (42%)
	Agree	12 (36%)	13 (39%)
	Somewhat Agree	4 (12%)	5 (15%)
	Neither Agree nor Disagree	0 (0%)	0 (0%)
	Somewhat Disagree	1 (3%)	1 (3%)
During the trial it was easy for me to complete the twice weekly (Wednesday and Sunday) bedtime activity diary			
	Strongly Agree	11 (33%)	12 (36%)
	Agree	20 (61%)	16 (48%)
	Somewhat Agree	2 (6%)	4 (12%)
	Neither Agree nor Disagree	0 (0%)	0 (0%)
	Somewhat Disagree	0 (0%)	1 (3%)
I was happy to receive questionnaires and updates via text message			
	Strongly Agree	24 (73%)	20 (61%)
	Agree	5 (15%)	11 (33%)
	Somewhat Agree	1 (3%)	1 (3%)
	Neither Agree nor Disagree	2 (6%)	0 (0%)
	Somewhat Disagree	1 (3%)	1 (3%)
I found it straightforward to use the Motion Watch to measure my child's physical activity and sleep			
	Strongly Agree	23 (70%)	19 (58%)
	Agree	8 (24%)	11 (33%)
	Somewhat Agree	1 (3%)	2 (6%)
	Neither Agree nor Disagree	0 (0%)	0 (0%)
	Somewhat Disagree	0 (0%)	1 (3%)
	Disagree	1 (3%)	0 (0%)
My child was happy to wear the Motion Watch during the day			

	Strongly Agree	10 (30%)	12 (36%)
	Agree	13 (39%)	14 (42%)
	Somewhat Agree	8 (24%)	4 (12%)
	Neither Agree nor Disagree	1 (3%)	1 (3%)
	Somewhat Disagree	0 (0%)	1 (3%)
	Disagree	1 (3%)	1 (3%)
My child was happy to wear the Motion Watch at night			
	Strongly Agree	15 (45%)	16 (48%)
	Agree	13 (39%)	14 (42%)
	Somewhat Agree	3 (9%)	2 (6%)
	Neither Agree nor Disagree	0 (0%)	1 (3%)
	Somewhat Disagree	0 (0%)	0 (0%)
	Disagree	2 (6%)	0 (0%)
I was able to complete the Sleep and Motion Watch Diary on most/all of the days my child was wearing the Motion Watch			
	Strongly Agree	15 (45%)	21 (64%)
	Agree	13 (39%)	8 (24%)
	Somewhat Agree	2 (6%)	0 (0%)
	Neither Agree nor Disagree	1 (3%)	1 (3%)
	Somewhat Disagree	1 (3%)	3 (9%)
	Disagree	1 (3%)	0 (0%)

Notes. Responses to questions where no answer was given are not displayed in the table.

Appendix F

Table 8: Debrief survey responses for PASTI and Bedtime Box groups summarising the benefits of the trial

Trial benefits questions	Response type	PASTI (N=33)	Bedtime Box (N=33)
I will continue to use the bedtime box with my child in the hour before bed now that the trial has finished			
	Strongly Agree	12 (36%)	9 (27%)
	Agree	8 (24%)	18 (55%)
	Somewhat Agree	7 (21%)	5 (15%)
	Neither Agree nor Disagree	4 (12%)	1 (3%)
	Somewhat Disagree	0 (0%)	0 (0%)
	Disagree	2 (6%)	0 (0%)
Taking part in this trial has been beneficial for me			
	Strongly Agree	14 (42%)	15 (45%)
	Agree	12 (36%)	18 (55%)
	Somewhat Agree	4 (12%)	0 (0%)
	Neither Agree nor Disagree	3 (9%)	0 (0%)
Taking part in this trial has been beneficial for my child			
	Strongly Agree	13 (39%)	13 (39%)
	Agree	14 (42%)	17 (52%)

	Somewhat Agree	2 (6%)	1 (3%)
	Neither Agree nor Disagree	4 (12%)	2 (6%)

Notes. Responses to questions where no answer was given are not displayed in the table.