ISRCTN58249751 https://doi.org/10.1186/ISRCTN58249751

Examining the feasibility of carrying out a parent-administered screen time intervention in toddlers

Submission date
27/04/2022

Recruitment status
No longer recruiting

Registration date
29/04/2022

Overall study status
Completed

Last Edited
02/12/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Sleep and attention are important for the development of children's health and behaviour. Over the past decade, there has been an increase in the availability and use of screen media in infants. However, currently very little is known about the impact of screen media on infant development. Some researchers have shown that toddlers who use more screen time have more sleep problems and wake more during the night. These problems appear to be greater when screen time is used immediately before bed. Similar findings have been reported in adults, where interventions designed to remove screen time have resulted in improvements in sleep. Research has also shown that toddlers who use more screen time have more attention problems and differences in how they use their attention. However, it is unclear whether screen exposure directly causes poor sleep and attention differences in toddlers. This study aims to look at the feasibility of running a 7-week pilot Parent-Administered Screen Time Intervention (PASTI) randomised control trial in toddlers who have screen time in the hour bed. This pilot trial will assess whether it's possible for caregivers to implement a screen time intervention with their child and pave the way for a large-scale trial that will test whether reducing toddlers screen time in the hour before bed has a positive impact on their sleep and attention.

Who can participate?
Caregivers who have a child aged 17 to 31 months at randomisation who has screen time in the hour before bed (please see the inclusion and exclusion criteria for further details)

What does the study involve?
First caregivers will provide consent and be asked to complete a Family Background Pre-screening Questionnaire to assess their eligibility to take part in the trial. If invited to take part in the trial, in the first 2 weeks caregivers will complete several baseline home assessments. These assessments include questionnaires about children's sleep, behaviour, development and pre-bedtime activities, as well as physical activity and sleep logging using an Actigraphy Motion Watch and diary. Caregivers will be asked to log their child's sleep for a period of 7-9 days. At the end of the home assessments, caregivers and their infants will visit the Birkbeck Babylab where they will take part in several measures of attention using a technique called eye-tracking and a

developmental assessment, which looks at language and motor skills.
Caregivers and their child will then be randomly assigned to one of three groups based on their child's age, sex and where their live, to make sure all groups are balanced. Caregivers will be put into a group where they are asked to either a) remove all screen time from their child in the hour before bed (PASTI group); b) engage their child in a range of pre-bed activities in the hour before bed (Bedtime Box group); or c) continue with their normal pre-bed activities (No Intervention group). Caregivers will be asked to deliver the intervention for a period of 7 weeks. During the intervention, caregivers in all arms will be asked to complete a bi-weekly Bedtime Activity Diary to report on the activities their child did in the hour before bed. In the PASTI group, caregivers will also be asked to complete a Screen Time Questionnaire on the days when they are not completing the diary to tell us about their child's use of screen time in the hour before bed. During the last two weeks of the trial (week 6 and week 7), caregivers will complete their follow up home and lab-based assessments which are identical to those described above. All caregivers in the PASTI Arm and Bedtime Box Arm will also be asked to complete a debrief questionnaire and a subset of caregivers in the PASTI arm will be invited to share their experiences of taking part in the trial via a semi-structured interview.

What are the possible benefits and risks of participating?
Taking part in this study will help the researchers to understand whether it is feasible for caregivers to implement a screen time intervention with their toddlers. In this trial, caregivers will be asked to remove screen time from their child in the hour before bed for a period of 7 weeks. In some cases this change in routine may cause mild stress, but any stress is expected to be minimal. Caregivers will be asked to put a Motion Watch on their child to log their physical activity and sleep. Skin reactions to the watch (e.g. eczema) are rare but could occur. During the lab visit caregivers and infants will take part in some activities that have been used regularly in other research studies. There is a small chance that the activities could make an infant fussy or upset and the session will be ended if this happens.

Where is the study run from?
Birkbeck, University of London (UK)

When is the study starting and how long is it expected to run for?
September 2021 to July 2023

Who is funding the study?
Nuffield Foundation (UK).

Who is the main contact?
Prof. Tim Smith, tim.smith@arts.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Tim Smith

Contact details
Creative Computing Institute, University of the Arts London, 45–65 Peckham Road
London

United Kingdom
SE5 8UF
None provided
tim.smith@arts.ac.uk

Additional identifiers

Protocol serial number
FR-000022056

Study information

Scientific Title
Parent-Administered Screen Time Intervention (PASTI): a 7-week three-arm assessor-blinded feasibility and pilot randomised controlled trial, compared to bedtime box intervention and no intervention (1:1:1) in toddlers

Acronym
PASTI

Study objectives
The aim is to demonstrate the feasibility of implementing PASTI through metrics of randomisation, retention, and intervention adherence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/01/2022, Birkbeck, University of London Research Ethics Committee (Malet Street, London, WC1E 7HX, UK; +44 (0)2030738044; ethics@psychology.bbk.ac.uk), ref: 2122037

Primary study design
Interventional

Study design
Three-arm assessor-blinded single-centre interventional feasibility and pilot randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
The impact of toddler screen time in the hour before bed on their sleep and attention

Interventions
Current intervention as of 22/07/2022:

The primary aim of the trial is to assess the feasibility of implementing a 7-week Parent-Administered Screen Time Intervention (PASTI), compared with a Bedtime Box Intervention and No Intervention, in infants who have parent-reported screen time in the hour before bed.

Participants will be randomised (1:1:1 allocation ratio) at the end of the baseline lab visit in a web-based randomisation system using minimisation with respect to child age, child sex, and family socioeconomic status (using the Index of Multiple Deprivation).

PASTI arm:
In the PASTI arm caregivers are required to remove screen time in the hour before bed from their child (range 17 – 31 months old). The PASTI is modelled on effective parent-education screen time interventions in older children (e.g. a 7-week intervention). A cover story for PASTI will be used to obscure the role of screen time to avoid self-selection of families interested in the topic and to minimise bias in caregiver-reported screen use across the intervention arms. As such, families will be recruited into our trial on toddler bedtime activities in the hour before bed (for full details, the trial protocol will be available on request). At the start of the intervention, families will receive 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 them displace screen time in the hour before bed (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). The activity cards for the PASTI arm contain a no screen time symbol, as well as suggested times for each activity card to aid with displacing screen time in the hour before bed. Caregivers will be asked to use toys /activities from the bedtime box with their infant in the hour before bed.

To examine the direct impact of screen exposure in the hour before bed on infants' sleep and attention control, the PASTI arm will be compared to two other modes of delivery.

Bedtime Box arm:
In the Bedtime Box arm caregivers will receive identical materials (i.e. Family Bedtime Box) to the PASTI Arm, but without any screen time guidance. In addition, the selection of activity cards will not contain a screen time symbol or a time suggestion for each activity. Caregivers will be asked to use toys/activities from the bedtime box with their infant in the hour before bed.

No Intervention arm:
In the No Intervention arm caregivers will not receive the Family Bedtime Box or any instructions to change their child's activities in the hour before bed or avoid screen time. The researchers expect pre-bedtime activities (such as feeding, playing, being read to, bathing and watching TV) to continue as usual.

———

Previous intervention:

The primary aim of the trial is to assess the feasibility of implementing a 7-week Parent-Administered Screen Time Intervention (PASTI), compared with a Bedtime Box Intervention and No Intervention, in 18-month-old infants who have parent-reported screen time in the hour before bed. Participants will be randomised (1:1:1 allocation ratio) at the end of the baseline lab visit in a web-based randomisation system using minimisation with respect to child age, child sex, and family socioeconomic status (using the Index of Multiple Deprivation).

PASTI arm:
In the PASTI arm caregivers are required to remove screen time in the hour before bed from their 18-month-old (range 17 – 19 months) child. The PASTI is modelled on effective parent-education screen time interventions in older children (e.g. a 7-week intervention). A cover story for PASTI will be used to obscure the role of screen time to avoid self-selection of families interested in the topic and to minimise bias in caregiver-reported screen use across the intervention arms. As such, families will be recruited into our trial on toddler bedtime activities

in the hour before bed (for full details, the trial protocol will be available on request). At the start of the intervention, families will receive 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 them displace screen time in the hour before bed (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). The activity cards for the PASTI arm contain a no screen time symbol, as well as suggested times for each activity card to aid with displacing screen time in the hour before bed. Caregivers will be asked to use toys/activities from the bedtime box with their infant in the hour before bed.

To examine the direct impact of screen exposure in the hour before bed on 18-month-olds' sleep and attention control, the PASTI arm will be compared to two other modes of delivery.

Bedtime Box arm:
In the Bedtime Box arm caregivers will receive identical materials (i.e. Family Bedtime Box) to the PASTI Arm, but without any screen time guidance. In addition, the selection of activity cards will not contain a screen time symbol or a time suggestion for each activity. Caregivers will be asked to use toys/activities from the bedtime box with their infant in the hour before bed.

No Intervention arm:
In the No Intervention arm caregivers will not receive the Family Bedtime Box or any instructions to change their child's activities in the hour before bed or avoid screen time. The researchers expect pre-bedtime activities (such as feeding, playing, being read to, bathing and watching TV) to continue as usual.

Intervention Type
Behavioural

Primary outcome(s)
1. Participation rates:
1.1. Number consented assessed at week -x to week -2 (pre-screen)
1.2. Number eligible assessed at week -x to week -2 (pre-screen)
1.3. Number probabilistically sampled assessed at week -x to week -2 (pre-screen)
1.4. Number randomised assessed at week 0
2. Recruitment pathways assessed at week -x to week -2 (pre-screen)
3. Intervention adherence in the PASTI Arm measured using the Screen Time Questionnaire and Bedtime Activity Diary over a period of 6 weeks (week 1 – week 6) during the intervention. In the PASTI Arm, the researchers will calculate and describe the average proportion of days with no screen time in the hour before bed, and the average duration of screen use in the hour before bed. These metrics will determine the design features for a future confirmatory study.
4. Participant retention measured using data completion rates at the follow-up lab timepoint (week 7)
5. The acceptability of PASTI measured using the Debrief Questionnaire and Debrief Interview after the follow-up lab timepoint (about week 8)
6. The acceptability of assessments measured using the Debrief Questionnaire and Debrief Interview after the follow-up lab timepoint (about week 8)

Metrics of feasibility study acceptability:
The researchers have chosen to implement a 'traffic light' system to assess the feasibility of implementing a full-scale PASTI trial. Performance metrics that fall in the Red zone indicate that a full trial following the current design may not be feasible, metrics that fall in the Amber zone

indicate that a full trial may be feasible but the protocol should be modified or the situation monitored closely, and metrics that fall in the Green zone indicate that a full trial is feasible and the researchers may continue without modifications to the current study design.

1. Randomisation (number of participants randomised overall):
a. Red zone: ≤73
b. Amber zone: 74 to 104
c. Green zone: ≥105

2. PASTI daily questionnaire completion (% of participants randomised to PASTI and retained to lab follow up that complete ≥60% of daily screen time questionnaires):
a. Red zone: <65%
b. Amber zone: 65% to 79%
c. Green zone: ≥80%

3. 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):
a. Red zone: <50%
b. Amber zone: 50% to 69%
c. Green zone: ≥70%

4. Retention (% of randomised participants attending follow-up Lab visit):
a. Red zone: <70%
b. Amber zone: 70% to 74%
c. Green zone: ≥75%

5. PASTI debrief questionnaire completion (% of participants randomised to PASTI that complete the debrief questionnaire measuring participant experience and assessment acceptability):
a. Red zone: <65%
b. Amber zone: 65% to 74%
c. Green zone: ≥75%

Key secondary outcome(s)

Current secondary outcome measures as of 29/03/2023:

Estimates for the following outcomes will be collected:
1. Total infant night-time sleep duration measured using actigraphy at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
2. Exogenous attention control measured using single search saccadic reaction time from the Visual Search Task at baseline (week 0; pre-randomisation) and follow up (week 7)
3. Average toddler screen use (minutes) in the hour before bed measured through one weekday and one weekend bi-weekly bedtime activity diary directly preceding the lab-based assessment at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
4. Additional sleep outcomes:
4.1. Average nap duration measured using actigraphy at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
4.2. Frequency of night awakenings measured using actigraphy at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
4.3. Sleep efficiency measured using actigraphy at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7).
4.4. Parent-reported sleep onset latency measured using the Brief Infant Sleep Questionnaire – Revised (BISQ-R) at baseline (week -1; pre-randomisation) and follow up (week 6)

5. Additional attention control outcomes:
5.1. Prosaccade saccadic reaction time and proportion of antisaccades measured using the Antisaccade Task at baseline (week 0; pre-randomisation) and follow up (week 7)
5.2. Baseline saccadic reaction time and disengagement saccadic reaction time measured using the Gap-Overlap Task at baseline (week 0; pre-randomisation) and follow up (week 7)
5.3. Parent-reported effortful control and inhibitory control measured using the Early Childhood Behaviour Questionnaire (ECBQ) at baseline (week -1; pre-randomisation) and follow up (week 6)

Previous secondary outcome measures:

Estimates for the following outcomes will be collected:
1. Total infant night-time sleep duration measured using actigraphy at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
2. Exogenous attention control measured using single search saccadic reaction time from the Visual Search Task at baseline (week 0; pre-randomisation) and follow up (week 7)
3. Average toddler screen use (minutes) in the hour before bed measured through one weekday and one weekend bi-weekly bedtime activity diary directly preceding the lab-based assessment at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
4. Additional sleep outcomes:
4.1. Average nap duration measured using actigraphy at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
4.2. Frequency of night awakenings measured using actigraphy at baseline (weeks -1 and 0; pre-randomisation) and follow up (weeks 6 and 7)
4.3. Parent-reported sleep onset latency measured using the Brief Infant Sleep Questionnaire – Revised (BISQ-R) at baseline (week -1; pre-randomisation) and follow up (week 6)
5. Additional attention control outcomes:
5.1. Prosaccade saccadic reaction time and proportion of antisaccades measured using the Antisaccade Task at baseline (week 0; pre-randomisation) and follow up (week 7)
5.2. Baseline saccadic reaction time and disengagement saccadic reaction time measured using the Gap-Overlap Task at baseline (week 0; pre-randomisation) and follow up (week 7)
5.3. Parent-reported effortful control and inhibitory control measured using the Early Childhood Behaviour Questionnaire (ECBQ) at baseline (week -1; pre-randomisation) and follow up (week 6)

Completion date
30/07/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/07/2022:

Inclusion criteria will be assessed using a Family Background Pre-screen Questionnaire. Potential participants will be invited to take part in PASTI if they meet the following inclusion criteria:
1. A family with an infant between 16 and 30 months at pre-screening
2. A family that lives in Central/Greater London and surrounding areas (within 75 miles of the Birkbeck Babylab)
3. A family that reports that their infant uses screen time in the hour before bed at pre-

screening. They must report that their infant uses ≥10 minutes of screen time in the hour before bed on ≥3 days of the week.
4. A caregiver is able to provide informed consent

___

Previous inclusion criteria:

Inclusion criteria will be assessed using a Family Background Pre-screen Questionnaire. Potential participants will be invited to take part in PASTI if they meet the following inclusion criteria:
1. A family with an infant between 16 and 18 months at pre-screening
2. A family that lives in Central/Greater London
3. A family that reports that their infant uses screen time in the hour before bed at pre-screening. They must report that their infant uses ≥10 minutes of screen time in the hour before bed on ≥3 days of the week.
4. A caregiver is able to provide informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
105

Key exclusion criteria
Exclusion criteria will be assessed using a Family Background Pre-screen Questionnaire. Potential participants will be excluded if they meet the following criteria:
1. A family with an infant who has a parent-reported genetic or neurological condition (e.g., Downs Syndrome)
2. A family with an infant who was born prematurely (<37 weeks)
3. A family with an infant who is taking part in another trial or research study

Date of first enrolment
25/07/2022

Date of final enrolment
05/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birkbeck College
Birkbeck College
Malet Street
London
United Kingdom
WC1E 7HX

Sponsor information

Organisation
Birkbeck, University of London

ROR
https://ror.org/02mb95055

Funder(s)

Funder type
Charity

Funder Name
Nuffield Foundation

Alternative Name(s)
NuffieldFound

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

At the end of the trial all outcome data, trial information, and necessary pseudo-anonymised personal data (e.g. family demographic, child age, gender, etc) will be made publically available via the Birkbeck Research Data repository. The data will be stored here indefinitely for public use. All types of data analysis will be possible. All participants will provide informed consent for the data to be stored on the Birkbeck Research Data repository. All other data, including the personally identifiable data in the master spreadsheet, will be retained internally on a secure Birkbeck data server.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/10/2024	24/10/2024	Yes	No
Dataset			02/12/2024	No	No
Protocol (other)	Version 3	29/03/2023	02/12/2024	No	No
Statistical Analysis Plan	version 1	31/05/2023	02/12/2024	No	No