Physical activity, sleep and physiological health in young children

A pilot study of a multisensory measurement and analysis

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ABSTRACT

Rationale: Early-life health behaviours such as physical activity and sleep are thought to shape longer-term health through two mechanisms: (i) by shaping developmental physiological and psychological processes; and (ii) by establishing health behaviour patterns and habits that track over time to adulthood. Through these mechanisms, early behaviours are increasingly hypothesized to influence life-course health and illness all the way to later years. To investigate the interactions between the early-life health behaviours, the proposed mechanism, and health outcomes, there is now a need for new methods that allow health behaviours and potentially related mechanisms to be objectively captured within young children's everyday contexts.

Aims: 1. To pilot a protocol for collecting in-depth, multimodal, concurrent accelerometry, heart rate, cortisol, and sleep data in young children in their everyday settings. 2. To develop and validate analytic methods for the resulting data.

Design: A multiple-cases, mixed methods, longitudinal observational study.

Participants: A purposive sample of 10-12 children (age 4-36m), and at least one of their parents, will be recruited through community partners outside the NHS. The children will be the index cases around which the data collection, analysis and synthesis will focus.

Measures: Data will be collected on: child's sociodemographic and parent-reported health and developmental statuses; child health behaviours and physiology; the children's everyday measurement context; and child, parent and researcher views. A combination of wearables (accelerometers, a heart rate monitor, an infant respiration, and position monitor) as well as direct observations by a researcher, ethnographic diary methods and parent interviews will be used.

Process: Data will be collected over seven consecutive days, including four phases: (i) an initial set-up with a short (2-3min) test recording; (ii) a brief (5-20min), lab-based, structured play session by the child and parent; (iii) unstructured, six-day, naturalistic multimodal data collection at home; and (iv) feedback to parents.

Analysis: Numeric data from the wearables will be analysed using advanced machine learning techniques, to explore, for each child, whether and how physical activity and sleep patterns relate to one another, and whether these further relate to stress experiences (HR, cortisol) during 24-hour and 7-day periods. Observations, and the transcribed parent interviews, will be analysed using content analysis, with codes and themes developed for deeper analysis alongside numeric results. Case study methods will be used to synthesise findings from the different types of data. Common learning points across the cases will be identified and used to further develop the measurement protocol.

Impact: This study is the first step towards a new data paradigm in early life ecological studies to increase evidence about early health behaviours, physiological and psychological processes, and long-term health *within the everyday context*. The results will advance a protocol for extended home-based, multimodal measurement of health and behaviour in young children, and advance analytical methods for processing multisensor data. Hypotheses generated will be progressed for further testing through subsequent, larger-scale studies.

Contents

1. INTRODUCTION

Early life from conception to age 5 years influences life-course health and wellbeing. Health behaviours such as early movement and physical activity, and sleep, are increasingly identified as potentially important. There is now strong evidence that they contribute significantly to children's current wellbeing; and increasing consideration of their long-term physiological, psychological and health impacts.

Moving forward, early health behaviours and related biopsychosocial mechanisms have the potential to provide highly novel insights and understandings that are embedded in the everyday realities of children and families, and that bring fundamental shifts in interventions and policy.

So far, we have generated key evidence-based hypotheses using existing longitudinal cohort data and new data which we have generated within existing measurement paradigm. To now move forward, we need a step change in how we measure early health behaviours and related physiological health outcomes. Specifically, we need objective (as opposed to the current, largely self-report), granular data on the key health behaviours in ways that meaningfully and recognisably relates with the children and families' subjective, contextualised perceptions of these behaviours (e.g. physical activity habits and routines within a typical 24-hour, 7-day-week period).

If we can quantify the health behaviours and physiological mechanisms and integrate findings about these with evidence about psychosocial mechanisms, context and health outcomes, then we will be able to answer questions about how early health behaviours – as experienced and enacted in real everyday life situations by children and families – relate to and shape objective physiological and psychological processes, and related health outcomes both presently and over time. This includes questions such as: How the cumulative amounts and patterns of early life movement and physical activity at home and in the community shape life-course trajectories for sleep, cognitive function and cardiovascular health? How early physical activity, sleep and stress interact, and shape later cardiometabolic and mental wellbeing trajectories; and how may these be helpfully targeted by early interventions? While measuring these data, and answering these questions, is increasingly common in adults and teenagers, this is very rare in younger children.

To move the research and knowledge forward, there is now a requirement for integration and advancement of new methods which have not yet been widely used in community settings and/or with young children but developed for diagnostic studies within healthcare or for older children and adults. This includes recording health behaviours (e.g. advanced movement sensor methods for quantifying physical activity, objective measurement of sleep) and physiological markers (e.g. cortisol and heart rate), as well as advanced machine learning techniques to clean, analyse and bring together the data from these.

Wearable sensors, such as accelerometers and heart rate monitors, have the potential to offer an objective record of many of the relevant physiological health variables in young children, and provide further inferences of wider key health outcomes such as cardiovascular health and stress. However, to use these techniques in early life studies requires that: (i) the sensors themselves are adapted for children, or paediatric sensors adapted for use outside the clinic, including calibration of the software associated with devices; (ii) data governance systems and frameworks are established that are acceptable for the gatekeepers, namely parents and carers; and (iii) data analysis techniques and models are developed or validated to take into the account the unique features of data in younger children (such as naturally large heterogeneity and rapid change as children develop at different rates). These challenges apply to almost all sensors and analytical techniques that currently exist; there are no off-the-shelf methods. For the kind of contextualised investigation outlined above, a

further challenge is to develop an analysis pipeline that integrates the data collected from each device and allows it to be interpreted and understood in the family context. Computational models of the biological processes that drive the relationships, for example, between physical activity, stress, and sleep, can combine data from different source devices and relate this to what we know of the underlying biology. However, this too would be novel and requires proof-of-concept research prior to taking to a larger funding proposal.

2. AIMS

The present project contributes to an overall purpose of developing wearable technologies to objectively and longitudinally measure young children's (≤5yrs) health behaviours and physiological states within their everyday activity and lives.

The specific aims of the present study are:

1. To pilot methods for collecting in-depth, multimodal, concurrent accelerometry, heart rate, cortisol, and sleep data in young children in their everyday settings.

2. To develop and validate analytic methods for the resulting data.

The specific questions the present study seeks to answer relate to both the feasibility of data collection and the quality of the data collected.

Table 1. Specific questions that the study seeks to answer

For the feasibility of data collection, key questions include:

1. What are the children and parents' views about the wearable devices being piloted, and how do their different features shape acceptability?
2. How feasible are the devices to use, by the child and parents, in and outside of home, at different points of the 24h activity cycle?
3. What devices and how do children and families want to combine into a measurement protocol that is feasible and acceptable to them?
4. What naturally occurring or researcher-instigated event(s) are feasible and acceptable to use to observe and elicit changes in physiological states?

For the quality of the data collected, key questions include:

1. What proportion of the ECG data is sufficiently noise-free so that we can calculate the HRV?
2. Is it possible to use unsupervised machine learning to segment and cluster the HRV, SC, and PA data collected using the devices?
3. Is it possible to estimate sleep stages from the respiration rate and ECG recorded by the Bittium/Napping pants?
4. How does the physiological data relate to events for, or actions of, the child? (as recorded through ethnography)
5. How reliable is the data from the devices used?

3. METHODS

DESIGN

The present study is a mixed methods, longitudinal observational study with multiple cases of young children (age 4-36m), and their parents. The children will be the index cases around which the data collection, analysis and synthesis will focus, and will be sampled through community partners outside the NHS.

POPULATION

We seek to recruit 10-12 children age 4-36m across developmental and health states. Young children are currently underrepresented in health research. The present study is part of a wider attempt to change this by developing methods that are better tuned to young children's everyday lives while also being safe, acceptable and feasible. As part of developing the protocol, careful consideration has been given to the features of young children as a study population, and how their specific features needs to shape the study design.

There will be no specific inclusion criteria for the children's developmental state, capacity, or health. The starting point is that all children meeting the age criterion (4-36m) will be eligible. Data will be collected on the children's developmental, health and sociodemographic features but these will not be used as an exclusion criterion. An exception is a strong reason to think that the devices used for data collection could negatively affected the child's health. Under this consideration, we expect to exclude children with allergies to the materials used in the devices, and children with metallic valves.

We will also include at least one of the children's parents. By 'parent' we mean an adult offering the everyday parenting care for the child (regardless of legal or biological status).

SAMPLING AND RECRUITMENT

Potential children and parents will be identified through existing partnerships. First, we will purposively sample children and parents from low resource areas through the Blyth and Northumberland Regeneration Project (PI: Robson). Second, we will sample children and parents through Newcastle community charity organisations (Children and Families Newcastle, Action for Children, Barnardo's, Children North East) that operate within low resource areas across North, East and West Newcastle and with whom we have existing, strong relationships.

We will ask the partners to identify eligible children and families as well as related community groups, and disseminate pre-prepared study materials to them, including recruitment packs directly to parents as well as posters and fliers made available through groups and community activities. These materials will include our contact details (email, telephone) as well as an expression of interest form with a self-addressed envelope with a stamp – the parents willing for their children to be approached about the study are invited to contact the study team. We will not access child or parent details directly, until the parents have first made contact with us.

From the expressions of interest from parents, we will organise a time to discuss the study with the children (where possible) and parents, to allow them to meet the researcher, to

provide more information about the study, and to allow them to ask questions and have those answered. Parents who are interested in taking part after having all their questions answered, will be recruited. The informed consent will be taken by the CI, or one of the research team following appropriate training and with clearly delegated responsibility.

We will enrol children and parents in the study as they are consented. We will use a diversity matrix to monitor sampling and recruitment. We seek to: include children across the age range (4-36m); prioritise recruitment of children from lower income contexts (using the IMD based on postcode); and include children across developmental capacities and ethnic backgrounds.

DATA COLLECTION - MEASURES

Data will be collected on: child behaviours and physiology; feasibility and acceptability of measurement; parent views; and context. Data collection is planned so that it includes three core data collection technologies and a further set of optional technologies (Table 2). This is to maximise child and parent choice, where the choices made will themselves provide data on feasibility and acceptability.

The four core data collection technologies will be: a questionnaire (sociodemographic and child development questions); a wearable sensor (the Bittium ECG with an inbuilt accelerometer); and brief direct observations by the researcher at the initial set up of the sensor. Agreeing to attempt these is a requirement for participant enrolment in the study.

The optional technologies are: a selection from among a further set of wearable sensors (napping pants, Emotibit, MAIJU suit); ethnographic diary methods; observations visit to join the family everyday activities by a researcher; and a further standardised parent questionnaire. These technologies are presented to the children and parents as optional additions that they are welcome to explore. We will gauge their reactions and note any views and questions they express, especially responses in terms of acceptability and feasibility. We will say to the children and parents that they are welcome to try these technologies if they so wish; but make it clear there is no requirement or expectation for them to do so. The children and parents may choose to explore any of these optional technologies, or not; at the time they will not be asked to give a reason for, or to elaborate, on their choice. It is unlikely to be feasible for a family to select all the optional technologies, and there is no expectation that any family would do so. We are primarily interested in their spontaneous reactions, choices and comments, which will form part of the brief observation at the set up.

Throughout, the sensor devices will form the quantitative data collection focused on physiology and directly measurable child behaviour, while the ethnographic data collection will focus on study participant usage, experience, approaches and attitudes and allow for witnessing first hand reactions and responses, as well as on contextualising the data on physiology and behaviours. Using these two approaches concurrently will broaden and deepen the enquiry and allow triangulation (use of the various methods and data sources to compare, contrast and complement one another).

Table 2. Variables, the related measures, resulting data, and evidence of feasibility

	Variables	Measure	Time required	Data	Previous evidence of feasibility
Core measures	Socio-demographics; Developmental capacity (motor, cognitive, social)	Questionnaire, incl. standardised PEDI-CAT[1] questionnaire	10min	Numeric, Textual, incl. subscale and total scores	Previously widely successfully used, including in similar 5-year NIHR ActiveCHILD Study by the research team
	Child behaviour and physiology	Bittium HR monitor	Up to 7 days	Heart rate variability, acceleration / movement, respiration rate, sleep	Used successfully for 2 days in children aged 4 – 14 years: https://doi.org/10.1186/s12911-020-01210-1 Used successfully for 32h (with a focus on sleep) in toddlers aged 14-32 months: https://doi.org/10.3390/s21227515 Used successfully in newborns in clinic for 6h: https://doi.org/10.3389/fphys.2019.00922
	Feasibility and acceptability, and measurement context	Brief observations at the initial set up, recorded using audio and a wearable camera	2x10min	Video recordings, textual transcriptions based on the audio	Previously widely successfully used in health and social research
Optional measures	Sleep quality	Napping pants	Overnight 3+ nights	Respiration rate	Previously used in infants (1-9 months)https://doi.org/10.1111/apa.15996
	Child behaviour and physiology	Emotibit wearable sensor Hair sample for cortisol measurement	Up to 6 hours	Heart rate variability, Skin conductance, Acceleration / movement	Emotibit - no evidence of previous use in children Hair cortisol – https://doi.org/10.1177%2F1099800417711583
	Movement types and capacity	MAIJU wearable accelerometer suit	Up to 24 hours	Acceleration at multiple body locations.	Previously used in 7 months old children in an observed short-term setting: https://doi.org/10.1038/s41598-019-56862-5
	Feasibility and acceptability, measurement context, parent views	Ethnographic diary methods	Up to 7 days	Textual, numeric data	Several, see e.g. publications by Rapley
		Observations from visiting researcher	Up to 4 hours		
	Executive function	Standardised questionnaire BRIEF-P	5min	Numeric data, total scores	Previously widely successfully used in health and social research

[1] Pediatric Evaluation of Childhood Disabillity Inventory (parent-completed)

DATA COLLECTION - PROCESS

Data collection will commence once the child and parent have been enrolled in the study, and all consenting processes completed. Data will be collected in four stages, each involving a quantitative and qualitative component: **Stage 1** will be the introduction and device setup at the lab; **Stage 2** a video-recorded structured play session at the lab; **Stage 3** a multi-day in-situ physiological and ethnographic recordings. The final stage, **Stage 4** a feedback session with parents, will be completed within three weeks from the end of the recording period for the family. The parent will be familiarised with the stages and the study process as part of the consenting (Supplement 1); and we will actively talk about the activities with the parent as we go through the stages.

Stage 1 Introduction and device setup in the lab

Key tasks:

- Build trust and rapport with the child and parent;
- Set the children up with the heart rate monitor; and
- Collect initial data on feasibility and acceptability.

Process description:
Child and at least one parent will attend the study lab (a room on the University premises, set up to be child friendly, with a small portable play area, and comfortable chairs for the family). The lead researcher (Thornton), with support from the CI (Kolehmainen, a very experienced child and family clinician and mixed methods researcher), will first welcome the child and parent, and take them through a set of activities (#1-4, below). The exact order of activities will depend on the child and parent preferences; but we will try to follow the same order, from 1 to 4, as far as is feasible whilst being sensitive to the child and family interests. A third, ethnographic researcher will be present but only to note observations of the situation and the process. Throughout, we will be transparent about who is present and why; will openly communicate with the child and parent about the actions and activities under way; and will actively check with both the child and parent about whether they are happy to continue or would prefer to pause or to stop (see Ethical considerations, in section 4).

Table 3. Overview of the Stage 1 key research tasks and procedures

1. A welcome to the child and family by Thornton and Kolehmainen; parent settling the child to play; and Thornton making the core data collection sensor (the heart rate monitor) available for the child and parent to familiarise with, if they so wish, among the play.
2. If/when the child and parent are comfortable to continue, Thornton will further explain the operation of the sensor and discuss any questions or concerns the family may have.
3. If the child and parent both remain comfortable and are happy to continue with the study, we will proceed to set the child up with the sensor, using established procedures recommended for the sensor.
4. Whether or not the device set up is successful, the child will be invited to continue to play freely, with the parent alongside and with them; if they are comfortable to do so. If the sensor set up has been successful, this play time will act as an initial test recording to check if the device is working as intended, as well as protected time for the parent to complete the core questionnaire.
5. After up to 10 minutes of free play, the Stage 1 initial set up will conclude. If the child and parent remain comfortable and happy to continue; stage 2 will commence. If not,

we will support the child and parent to move directly to stage 4, feedback or to leave, whichever is their preference.

Key outputs:
The ethnographer's observations about the processes, feasibility, and acceptability; and whether or not it has been possible to set the child up with the heart rate monitor so that it is recording data.

Stage 2 Video-recorded, structured play session

Key tasks:
- To ensure the child and parent are comfortable with the sensors;
- To complete all core data collection; and
- To collect detailed, video-recorded information for labelling and contextualisation of the heart rate data.

Process description:
For children and parents who remain comfortable and happy to continue, we will next invite them to join a more structured play area, placed in the same room but kept behind a screen until Stage 2. The structured play area will consist of a set of simple, developmentally appropriate tasks of varying physical intensities. The tasks are set up so that they are hypothesised to result in different physiological states to aid calibration. Three levels of tasks are used: base level (minimum physiological load); light activity; and intensive activity (Table 4). We will work with the parent and the child to introduce the tasks from base level to light activity to intensive activity; following the child and parent's lead. The CI (Kolehmainen), as an Honorary Consultant Allied Health Professional in paediatrics, has extensive community-practice experience of scaffolding similar activities with children across a range of ages and abilities, and with their parents. She will take the lead on this and is highly experienced in doing this in a way that is fun and enjoyable for the child, and allows the activities to take place in the safe bond between the child and the parent.

In addition to the three levels of structured tasks that we will set up, any stress responses by the child, at any point, will be noted. **We will never seek to introduce stress to a child, and will work closely with the parent to ensure the child is comfortable.** However, given the age of the study population, we recognise children of this age often use displays of stress as developmentally appropriate means to communicate their preferences, and thus we consider it important to describe this as part of the protocol – to aid our labelling of it, was it to occur. We will actively encourage the child's parent to point out and label any stress or discomfort by the child; the parent will be best placed to recognise this, and to act on it.

The structured play session will run up to around 10 minutes; depending on the child's preferences. The session will be video-recorded to allow subsequent, accurate labelling of the heart rate monitor data by activities that the child was engaged during the recording. This labelling will enable an initial assessment of the validity of the heart rate data, as well as provide a frame for contextualising the further heart rate data recorded in-situ, in the child's real-life environment.

The end of the structured play session will conclude the initial data collection using the core technologies. At this point, the child and parent will be presented with three options:

1) If they remain comfortable and happy to continue, they can choose to explore some of the optional data collection technologies. This is for as short or long they wish, and they can do this in whatever way they would like to (e.g. continuing play on the floor; while the child is feeding or napping; or by taking things home with them). If the family so wishes, more details will be provided.

2) If they remain happy to continue in the study, but wish to end the present session, they can now leave wearing the heart rate monitor the child has been set up with. We will remind them of the instructions for wearing it; provide them with accessible, written instructions to take home; and arrange to check in with them later the same day by phone (if they are happy with this).
3) If they'd prefer not to continue with the study, we help them to remove the heart rate monitor, thank them, and organise a feedback session with them at their convenience.

Table 4. Three levels of structured, developmentally appropriate tasks; and a description that will be used to recognise displays of stress

	Generic task description[2]	**Physiological signs**	**Behavioural signs**
Base Level	Sitting, either supported or unaided, e.g. on parent's lap or on the floor, may have their head supported	Normal heart rate Relaxed muscles	Looks comfortable and relaxed, quiet with little verbalisation, very little body or limb movements
Light Activity	A standing, or another upright, position while playing with a sensory activity of a child's choice (e.g. sand, water, clay, visual).	Slight increase of heart rate Slight change of skin conductance More active muscle engagement and increased tone, to maintain posture	Increased alertness and attention Potentially increased self-expression (incl. sounds) More active movement of limbs If able, turning of head
Intense Activity	Whole body movements, where possible against resistance (e.g. parent swinging and bouncing the child; the child crawling, climbing up soft steps, walking, running)	Substantially increased heart rate from base level Increased body temperature and skin conductance Noticeably increased tone	Increased acceleration, of body and/or limbs Clearly increased alertness and vocalisation (laugh, chatting)
Displays of stress by the child	n/a	Increased heart rate Increased temperature, skin conductance, and sweating. Noticeable changes in tone (e.g. flailing limbs, losing body posture)	Actively searching for caregiver Facial expression of worry, overwhelm, displeasure Increased arousal, vocalisation

[2] The actual task selected for an individual child will depend on the child's developmental level, determined by the earlier parent PEDI-CAT questionnaire from Stage 1

Key outputs:
Sufficient data to begin to answer some of the feasibility, acceptability and data quality questions; children and families who are happy to continue in the study are set up for the everyday data collection.

Stage 3 At-home recordings

Key tasks:
- Child continues wearing the core sensor (heart rate monitor), for as long as they and their parent are comfortable, up to a maximum of seven days, while living their usual everyday lives and undertaking their everyday activities;
- Parents who opt in for them, complete ethnographic diaries, and/or an executive functioning questionnaire for their child;

- The ethnographer researcher (Hunter) completes further observations and piloting of sensor(s) with children and families who opt in for these optional data collection; and
- Parent hands back the sensor at the end of the recording period (maximum seven days), and parents who opt-in for it, provide a child hair sample (Supplement 2).

Process description:
Throughout this phase, the research team will proactively keep in contact with the parent(s) using their preferred mode of communication (e.g. in our previous studies usually a text, sometimes phone and/or email). The focus will be on checking the child and parent are comfortable; emphasising that the child and parents should stop data collection at any point if they feel at all hesitant to continue (i.e. they should hold a low bar for stopping, and they do not need to complete seven days); and reassuring the parent(s) that the research team is available for contact at any time should they have questions or concerns.

Ethnographic methods, including diary data collection where parents and children will collect their own diary entries detailing their everyday experiences and thoughts, are offered as an optional way for children and parents to contribute their perspectives and lived experiences to the study.

Table 5. Summary of the instructions for data collection during the at-home recording

Data collection		**Key instructions for the parent**	**Stopping data collection**
The heart rate monitor		▪ This can be worn day and night (24-hours a day).	*Data collection should stop and the device should be removed if:* ▪ At any point the child is uncomfortable wearing the sensors (including any itching or rash around the site). ▪ The child indicates they do not want to wear the sensor. ▪ The parent has worries about or feels uncomfortable about the wearing of the sensor, or the data collection. ▪ If any part of the sensor appears broken, loose, or in any way "not right", it should be removed. The parent should also contact the research team. ▪ The device is causing any other issues for the parent or child, or is preventing parent or child from doing their usual activities.
Optional (parents can choose some of these if they so wish)	The MAIJU	▪ This can be worn at any point during the day or night. ▪ The suit can be worn on top, or under, other clothes. ▪ The suit can be washed if soiled, but the sensors need to be removed before washing.	
	The napping pants	▪ This is worn during the night.	
	Ethnographic diaries	▪ Parent completes at least daily ▪ Can also involve the child, and do together ▪ Note activities, events, thoughts, feelings ▪ Include activities for parent and child ▪ Can write text, and include photos or video	▪ Parent chooses if/when they want to make an entry, stopping rules n/a.
	A researcher visit	▪ In days 2-4 of home recording, a visit by a researcher in the team ▪ Lasting up to 4 hours ▪ On a day and time preferred by the family	*Data collection should stop and the researcher bring the visit to an end if:* ▪ The family indicates they no longer wish to continue or take part. ▪ The researcher judges, based on child or parent cues, that the child

		▪ "Short ethnography": the researcher will join the family during their everyday life, spend time with families, joining usual daily life activities ▪ Their aim is to see and learn about what the child's everyday life, and collect notes of the everyday activities and events ▪ The researcher will listen to the child, the parent, and other people present, and may ask questions to better understand them ("unstructured interviewing"). ▪ From this, the researcher will write a narrative that helps to better describe and make sense of the information recorded by the sensor data ▪ This also helps to gain further insight from child and parent.	and/or the family requires space and it is time to bring the visit to an end. ▪ The researcher feels unsafe in the environment. Open, ongoing dialogue between the researcher, parent and child will be key for ensuring the visits do not run for too long.
Returning the sensor		▪ The parent and researchers will arrange a mutually convenient time and way for the research team to collect the sensor (and any diary materials). ▪ The researcher will also invite the child (if appropriate) and parent to reflect on their experience and provide any immediate feedback.	n/a

Key outputs:
Data from core, and any optional, technologies to answer the research questions, including all the questions related to feasibility and acceptability as well as data quality.

Stage 4 Feedback to the parents

We will provide feedback to parents on their child's data within 2-3 weeks from the end of their recording (or sooner, if possible). This will incorporate aspects of participant "debriefing", however, we will not undertake formal debriefing as the participants are already actively and transparently engaged throughout the process, and any issues picked up and addressed throughout.

In the feedback, we will reiterate the aims and research questions of the study, and share with the parent(s) accessible summary details of the data we managed to capture about their child, including illustrative summary items in terms of what these data mean. The materials provided will include a graphical visualisation of the data recorded from each child, potentially showing how their physical activity, heart rate variability, and sleep evolved through each day of the study. We will also share with the parent(s) the anonymised ethnographic summary narrative, and provide them opportunities to comment on this. We will encourage and facilitate them to ask questions about the study and about the data collected, and we will openly welcome their thoughts, critique and suggestions.

This feedback session concludes the child and parent's participation in the study. After this, we will continue to share wider, anonymised and summary findings with the parent(s).

DATA PROCESSING

The initial data cleaning and processing will happen within three data streams: (i) the quantitative data from the questionnaires; (ii) the quantitative data from the sensor devices; and (iii) the ethnographic data (parent diaries and researcher observations).

Quantitative data from questionnaires will be recorded electronically, and stored immediately on the secure Newcastle University storage area. They will be cleaned to ensure that all entries correspond to a child within the study (no tests or duplicates). The standardised questionnaire data (PEDI-CAT, BRIEF-P) will be processed and scored according to their respective manuals.

Data from the sensor devices will be downloaded directly to secure storage immediately upon receipt. Researchers will perform an initial check of validity, ensuring accurate data was collected and that there were no operational issues with the device. If there were, we will make note of this to discuss with parents in attempt to understand why, and feed this into our analysis of the acceptability of devices. Bittium data will be processed to detect any periods of non-wear time, to calculate the heart rate and heart rate variability, and to calculate the Euclidean Norm Minus One (ENMO) of the triaxial acceleration. Data from the Napping Pants, and the MAIJU Wearable accelerometer suit will be processed using the software developed by their development team. Emotibit data will be parsed using the Emotibit data parser, then processed to calculate heart rate and heart rate variability from the photoplethysmography signal, the ENMO of the acceleration, and the skin conductance level from the electrodermal activity.

The ethnographic and qualitative data will consist of detailed field notes, a researcher diary, and observation notes for each family. These will be recorded manually with pen and pad, for ease of collection and to facilitate a more 'informal' setting between researcher and the families. This process will be explained to parents and the content of the notes accessible to them should they wish to read or sense check. The notes will be kept utilising pseudonyms so that participants are not identifiable. The notes will be kept on the researcher's person at all times during the active data collection, and taken to Newcastle University and stored securely in a locked drawer, at the Newcastle University research office base. In addition, families may opt in to keep a multi-media ethnographic diary. This will be completed by parents, with additions from the children, designed to be interactive and completed using a variety of materials that we will provide. Digital images will be taken of the content (e.g. child's drawing) and uploaded onto a secure storage, with identifiable data omitted. All these ethnographic data will be subsequently digitalised and stored in a secure Newcastle University location, accessible only a core subset of the study team (Hunter, Kolehmainen, Thornton, Rapley, Robson), in preparation for analysis. The data will then be transcribed, and data related to each child analysed individually using case study approach, identifying topics and themes, exploring wider commonalities and divergencies. Established quality assurance techniques will be used. This will ultimately result in each child and their family having an individual ethnographic case study narrative that will be used to provide comprehensive and rich, contextualised, insights into their use and experience of the wearables and the study processes. To these, additional analysis frameworks can be applied in order to develop robust foundations for wearable sensor strategies.

DATA ANALYSIS AND SYNTHESIS

The processed data will be analysed in relation to the main research objectives, aided by the questions related to acceptability and feasibility, and to data quality.

Acceptability and feasibility analysis will consider both the devices and the process, and will draw on a range of data, including: the response rate, dropout rate, and ethnographic observations and child and parent responses throughout. We will assess the overall acceptability of the core device by counting the number of participants who agreed to try wearing it, the number who managed to wear it home, and the average length of time it was worn. Optional devices will be assessed in a similar manner but with the acknowledgement that they were not presented as a core part of the research and may have had more uptake if they had been. We will bring together these quantitative data with the ethnographic data to build a picture of participant experience, including potential reasons for not taking up, or discontinuation of, device usage, as well as ways in which the devices or the process could be improved. We will use the data to better understand if some elements (devices, or process) are more acceptable than others, and why this may be.

To answer questions about the quality of the physiological measurement we will calculate the proportion of signal for which we have sufficient data quality to derive the measures of interest. For the Bittium Faros heart rate monitor this will be the heart rate, heart rate variability, and sleep stage; for the Emotibit this will be the heart rate, heart rate variability, and electrodermal activity; for the MAIJU suit this will be the posture and movement type; for the napping pants this will be sleep stage.

To answer questions about the relationships between physiology, behaviours and related everyday contexts, we will initially bring together the physiological signals (HR, HRV) with the behavioural signal (acceleration) using the hidden semi-Markov model (HSMM) unsupervised machine learning approach outlined previously (Thornton et al., 2022). This will find the characteristic states of physical activity (PA) and heart rate variability (HRV) that each child has, and allow us to chart how the child moves from state to state throughout the recording. Using this, we can investigate the relationships between the physiological (HRV) and the behavioural (PA) by describing the characteristics of the states the child spends time in. This analysis will be run for each child individually – to provide the characteristic states of the child, but also for the population as a whole – to provide characteristic states that may be more representative of a wider population. We will then supplement the analysis with the ethnographic narratives, to provide ethnographic interpretation of the child's emotional state, behaviour, experiences, and the surrounding context, alongside the characteristic states identified by the machine learning model. This will be illustrated as a timeline of key observations, contexts and events alongside the characteristic HSMM states detected during the ethnography. As well as allowing a human interpretation of the states, this will also allow us to relate important contextual or behavioural changes to state transitions, producing an intimate insight into the emotional dynamics of the child and interpret the datasets alongside each other.

SAMPLE SIZE

We will seek a sample size of 10-12 families. This is based on a combination of feasibility and what is likely required to meet the study aims, reflecting the feasibility nature of the study. Data will be collected from only one case (a child and their family) at a time to enable accumulation of knowledge in terms of the study procedure from one case to the next. The analysis will not seek to do any subgroup analyses.

For exploring feasibility and acceptability, 10-12 cases (clusters of the child and their family) is within the common range of sample sizes and a recommended rule of thumb for small pilot studies (Julious, 2005). 10-12 children will also provide sufficient data to estimate rates of noise and anomalous recording (to explore data quality), and to use as testing data for the analysis methods.

Relating physiology to behaviour and context will be done within a case, with the focus on seeking to understand these interactions for within each child and in relation to their context. Here the sample size will be defined by the duration of recording. If we find that aggregate analysis may be appropriate (for example if relating PA to HRV), random effects meta-analysis will be used following (Vieira et al., 2017).

4. STUDY MANAGEMENT

ETHICAL CONSIDERATIONS

Ethics approval will be obtained through the Newcastle University Ethics committee (application via https://newcastle-ethics.limequery.com/296746).

The broad position to including young children as study participants

The present research is aimed to benefit children, and to give young children increased and more meaningful ways to contribute to research about their lives. It is already well-established that good quality research, using appropriate methods tuned with children and young people's lives, is essential for finding out how to improve their health, care and lives (Nuffield Council on Bioethics, 2015). Children continuously express that they believe research is important, and that children should be provided the option to take part in research to help to understand their daily life patterns and improve their life-course health.

In research with children, including young children, it is important to consider children as their own entities and to involve data from the children themselves (not just from their parents and carers). As their own entities, children have rights, including the right to make a contribution. The current understanding of childhood also suggests that children actively generate their own worlds (Opie & Opie, 2000) as opposed to merely exist in context created for them; and that different children experience the world differently (European Centre, 1994). Without collecting data directly from children themselves, there is risk that the data: will not be relevant to the children; does not accurately reflect the children's own perspectives; will result in policies and interventions that are not acceptable to them; or will not address the right issues. In other words, there is a risk that the relevance, acceptability and validity of the results will be compromised.

In research with children, children's right to make a contribution need to be considered together with their right to be safe from harm. It is a common concern that children may be vulnerable in research. A report by the Nuffield Council on Bioethics recommended that the best way of ensuring that children do not become vulnerable in research is to involve children and/or their parents in designing study protocols, and to ensure that they are enabled to make informed decisions throughout the research process. The nature of their involvement and enablement depends on the population of children (e.g. their capabilities and interests) and the nature of the research. This means giving special considerations to the ethical, and related scientific, issues; in addition to the usual ethical and scientific considerations required.

As a result of enacting these considerations in the present study, we have agreed some key principles that will guide our research. These are based on the current recommendations on ethical research with children, where the recommendations themselves have had input from children and parents (Nuffield Council on Bioethics, 2015).

- Children will be respected and appreciated as important contributors without whom the project would have limited meaning.
- The procedures for recruitment, consent/assent, and data collection have been designed to be sensitive for young children's views about whether they wish to contribute, and how they may wish to contribute.
- Active steps will be taken to conduct the research so that children will be empowered to participate on their own terms and within their developmental abilities. This includes the use of 'child-friendly' research methods that are in-tune with children's

ways of experiencing the world; and building choice by the children and their parents into the study processes themselves.
- Information about the outcomes of the research will be fed back to children and parents in ways that are accessible and understood by them.

The proposed research focuses on young children who are unlikely to be able to make fully informed choices about their participation in research, and who are likely to have limited attention span and understanding for contributing directly to the research design. The Nuffield report recommends that in these circumstances the children's parents are usually best placed to inform the research and make decisions on their children's behalf. However, the children should also have opportunities to be involved in ways that their capacity allows them.

Specific actions to minimise any risk of harm

We do not anticipate the study methods or processes to cause harm. However, we believe it is important to always be alert and open to any unanticipated negative consequences, or contextual changes that may affect participants' involvement in the study.

Based on our experience of studies with young children and their parents, including previous studies using wearables sensors and a previous pilot study with everyday ethnography, we will put in place specific actions and procedures, throughout the study, to ensure we are well placed to identify and address any issues early (Table 6). Through this we will minimise any risk of harm for children and parents.

Table 6. Specific actions we will put in place to actively identify and mitigate any issues or harms

- Good relationships and trust will be proactively built with both children and parents to facilitate open communication and reduce any worry about the research.
- Parents will be provided with clear information about the study and will be encouraged to clarify any question before they are asked to take part to enable them to make the best choice for their children.
- The information to parents will include fair representation of the likely risks, burdens, and benefits of the study, weighed up from the perspective of potential participants as advised by the Parent Advisors.
- Potential participants will be offered opportunities to discuss the studies appropriately and sensitively so that they are able to make free and informed choices about whether to take part with emphasis on the voluntary consenting.
- One of children's parents will be asked to provide written consent; however, after this we will continue to proactively seek for assent from both the child and parent, and will be sensitive to any signs that either of them will not wish to continue to the data collection or the study.
- Children will be given as much control over their participation as possible and will be encouraged to take part in ways that they prefer. Sensitivity will be shown to their preferences not to participate (ongoing 'assent').
- We will encourage parents to be sensitive to their children's cues and signs, and to openly articulate when their child seems to prefer not to continue with an activity or data collection. We will emphasise, at all times, that the child's happiness and contentment is paramount; and children should not be persuaded or pressurised to participate.
- Parents will be encouraged to allow their children to choose which sensor devices to wear, if any.
- The context of any data collection with children will be carefully considered, all relevant information obtained will be fully disclosed and the right to privacy and anonymity will be respected throughout the project.
- All data will be made non-identifiable as far as possible; and any publications resulting from the study will only use non-identifiable data and summary descriptions.
- A telephone number for a 24/7 line will be made available for the parent for the duration of the data collection. They are encouraged to use this to can contact the research team for any uncertainties and enquiries, including evenings and weekends.
- The study CI (Kolehmainen) will be available to the parents and the wider research team at all times during any data collection period. As a highly experienced clinician and senior researcher, she will take the responsibility on ensuring the researchers interacting with children and parents are appropriately trained and supported.
- We do not anticipate harms or risks related to the study procedure, the will take the decisions about any onwards referrals of concerns
- In obtaining informed consent, the investigator will comply with the applicable regulatory requirements, including the Conference of Harmonization Guideline for Good Clinical Practice (ICH GCP), the ethical principles that have their origin in the declaration of Helsinki, any local ethical guidelines and professional codes of conduct.

RESEARCH TEAM

The day-to-day research team consists of Kolehmainen (CI), Thornton (the PI and day-to-day lead), and Hunter (ethnographer). They will be further supported, for specific technical, topic and methodological expertise, by the wider study team (Table 7).

Dr Kolehmainen has extensive experience of interacting with children of all ages through her clinical, research, and voluntary sector experiences. She has advanced skills in building good relationships with children and their parents, including in building a high level of trust and confidence, listening to both the child and their parents, and dealing with sensitive issues in a manner that is respectful and empowering of all parties involved, including the child. Dr Kolehmainen has received specific training about discussing research with children and families for the purpose of consent/assent; and is trained in appropriate safeguarding procedures.

Dr Thornton has significant experience working with sensitive health related data collected from children. As part of the present project, he will receive further external training in safeguarding, as well as training in the use of the heart rate monitors by Dr Eggett.

Ms Hunter is a qualitative researcher with experience in interacting with children in professional and voluntary sector capacities, including new mothers and babies in breastfeeding and sleep studies. She has particular experience in building rapport with participants, engagement, discussing sensitive matters and responding to participant needs. Involvement in the project, will also form a part of her further, pre-doctoral research training funded by the NIHR/HEE as part of an external fellowship.

Table 7. Full project team: expertise, roles, responsibilities

Person	**Expertise**	**Roles**	**Responsibilities**
Niina Kolehmainen	Study Design, Health Behaviours, Child health	Overall Study Design, conduct and Supervision Participant recruitment and retention	Research ethics and governance (overall responsibility as the CI) Staff supervision and training Safety, and reporting
Chris Thornton	Sensors/Devices, Data Analysis, Neurophysiology	Day-to-day study Management, Device Data Collections (e.g. to acquire and prepare all devices, to fit devices during study, to troubleshoot issues with devices, to download and securely store all data collected)	Data Management Device Maintenance
Emily Hunter	Ethnographic Methods, Qualitative Methods, Participant Engagement	Qualitative Data Collection, PPI	Ethnographic data collection and analysis
Abigail Collins	Cardiac physiology	Student	Selected, quantitative data collection and analysis with supervision from Thornton
Christopher Eggett	Cardiac physiology	Co-investigator	Physiology expertise to the study team

Craig Williams	Paediatric physiology	Co-investigator	Physiology expertise to the study team
Tim Rapley	Qualitative methods	Collaborator/Supervisor for Hunter	Methodology supervision of Emily Hunter, with the CI
Ian Robson	Qualitative methods	Collaborator	n/a

Newcastle, Northumbria and Exeter Universities are internationally leading centres in research into everyday patterns of health behaviour, including in children, and the mechanisms through which these may relate to wider health and illness. Collectively, our particular strengths are: (i) in-depth, intensive and data-rich longitudinal observations in ecologically valid everyday life situations – including novel remote sensing and AI tools; and (ii) interdisciplinary inquiry across clinical and population health – i.e. collecting, comparing and integrating observations from people with a wide range of abilities and health states through clinics, homes and community settings.

DATA MANAGEMENT

Please see Supplement 2, as well as the data management plan stored here:

https://newcastle.sharepoint.com/:w:/r/sites/WEARable/Shared%20Documents/General/3.%20Protocol/Data_Management_Plan.docx?d=wa0c6413e9bb5485cafb3a532cb1ee1ac&csf=1&web=1&e=aatpXv

AUTHORSHIP

Everyone named as contributors or authors in this protocol have already made a significant intellectual contribution to the design of the study, and will be invited to contribute to data analysis and interpretation, as well as to author resulting papers. Authorship will follow the guidelines provided by the ICMJE regarding authorship principles: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

The anticipated manuscripts include:

- The feasibility and acceptability of monitoring 24h movement, heart rate, and sleep in young children in their natural environments. Target journal: BMC Pilot and Feasibility Studies. Lead authors: Thornton/Kolehmainen.
- Understanding the interactions between physical activity, heart rate, and heart rate variability in young children (4–36 months): an unsupervised machine learning approach. Target journal: BMC Digital Health. Lead author: Thornton.
- Combining ethnography and wearable sensors to study the everyday of young children. Target journal: BMJ Paediatrics Open. Lead author: Hunter.
- Observing the Everyday: ethnography and wearable sensors for investigating child health and behaviours in context. Target journal: BMC Methodology. Lead author: Hunter.

- Reflexive practical epistemology of co-producing interdisciplinary ethnographic and biometric data. Target journal: tbc. Lead author: Robson

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Supplement 1. Materials for parents and children

The following materials will be provided to parents as part of informing potential and interested parents about the study. These materials follow templates co-designed by parents and previously, successfully used by us in several similar studies.

- Parent cover letter and return slip
- Participant information sheets – parents' A5 flier leaflet
- A4 summary of the research steps
- Consent forms sample

The above will include a link to the study website, which will host further materials and details, including further details on: data access, use and storage; the technologies and sensors used; risk considerations; and insurance (for details, see Supplement 2).

S1: Parent cover letter and return slip

[on Newcastle University headed paper, with relevant community partner logos]

Date:

Dear Parent,

Moving, sleeping and pumping hearts: a WEARables study with young children

We would like to invite you and your child to take part in a research study. The study seeks to better understand how young children move and sleep in their normal lives, and how that affects their hearts and their wellbeing. The study focuses on children under 3 years.

I have included child and parent fliers about the study. You can also access full information about the study here: [add website]. This includes full details about what information we'd like to collect, how and from whom.

If you are interested in hearing more or taking part, please contact one of us, Niina or Emily, by:

Phone: 0796 4329630
Email: niina.kolehmainen@newcastle.ac.uk or emily.hunter@newcastle.ac.uk

I have also attached a return slip and a self-addressed envelope – you can also contact us by returning the slip, and we will follow up with you. You and your child are under no obligation to take part.

The study is a collaboration between Newcastle University and wider partners across Northumbria and Exeter.

Thank you for taking the time to consider this study.

Yours sincerely

[Name and position / title of the person or organisation disseminating materials]

RETURN SLIP

The research team does not currently hold any details of you or your child.

If you would like to hear more about the study, you can ask for the team to contact you by returning this slip.

☐ I am interested in this study and would like to know more about taking part

☐ I don't wish to participate, but would like to receive summaries of the findings

For contact, or to send summaries of the research, please include your preferred details:

Name: _____

Address: _____

Telephone number: _____

Email: _____

Information on this page will be stored securely, and separately from all other information that you and/or your child may provide.

We will keep this information confidential and will not share it with anyone outside the immediate research team.

S1: Participant information sheets – parents' A5 flier leaflet

Please refer to a separate pdf. We may use this information in different layouts and formats, and with different visuals – co-designed with the contacts through whom the recruitment will take place.

S1: A4 summary of the research steps

This detailed information about data collection will be made openly available via the study website, and also shared and discussed with all parents before consenting.

What will the research involve?

The study involves up to four steps. If you decide to take part, you and your child can stop at any of the steps – you do not have to go through all of them. You can also choose to skip steps, and you can make those decisions at any time.

Steps 1 and 2 happen at the University, on a single visit lasting 60-90 minutes.

Step 1: Is to meet us in person, to get setup for the study.

- Get to know the researchers.
- Introduce your child to a heart rate monitor and allow you to take a look at other possible technologies.
- Collect initial information about how the heart rate monitor is working, and what you and your child think about wearing it.

Step 2: If you and your child are happy to continue, we will also invite you to do a short, 10-minute, video-recorded play session with your child.

- To ensure you and your child are comfortable with the heart rate monitor and any other technology you may choose.
- To collect more detailed information about how your child's movements might relate to their heart rate, and
- For you to complete a further questionnaire.

After step 2, if you are happy to continue, you can take the heart rate monitor and any other technologies home with you. From home, you can continue to take part in the study for up to seven days. This is with support from us.

Step 3 At home measurement:

- Your child can continue to wear the heart rate monitor for as long as they and you are comfortable (up to a maximum of seven days) while living their usual everyday activities.
- Parents who opt in for them, can complete diaries, and/or a further questionnaire.
- A researcher (Emily) with particular experience in doing research alongside families will visit children and families who opt in for a visit.
- Parent hands back the sensor at the end of the recording period (maximum seven days), and parents who opt-in for it, will provide a hair sample for their child.

Step 4 a feedback session with you, at your preferred location.

- We will provide feedback to you on your child's specific data
- This will be within 2-3 weeks from the end of your study participation.

S1: Consent forms

To be placed on NU headed paper

CONSENT FORM

Project title: Physical activity, sleep and physiological health in young children

Researcher's name (the person taking consent): Niina Kolehmainen / Christopher Thornton

		Please initial the box
1	I confirm that I have read and understand the information sheet for the study. I have had the opportunity to consider the information and ask questions, and I have had my questions answered satisfactorily.	
2	I understand that my decision is voluntary and that I am free to change my mind at any time, without giving any reason, without my legal rights or my child's health care being affected.	
3	I agree to my child and I participating in the study.	
4	I agree to provide the research team information about my child's development and sociodemographic details.	
5	I understand that the study may involve follow-up, and I am willing for the research team to contact me for this.	
6	I agree the research team to approach me for a visit to my house, and an interview about mine and my child's experience throughout the study. I can still decline to take part after discussing it with them.	
7	I agree for an anonymised sub-selection of the data that I and my family provide to be made available for further research use. This is only for data that cannot be linked back to me or my child.	
8	I understand that the data collected during the study may be looked at for monitoring purposes. This may involve individuals from the Newcastle University, from regulatory authorities.	

_____ _____

Name and signature of the parent Date

_____ _____

Name and signature of the researcher Date

When completed, provide one copy to the parent and place the original in the research file

Participant Consent Form – Cortisol Measurement

Please complete this consent form if you wish to take part in the study.

	Please tick
1. Taking part: • I agree that I have read the participant information leaflet and understand what the study is about and what mine and my child's involvement will be. I have had the opportunity to ask questions and have had them answered appropriately.	
• I understand that mine and my child's participation is voluntary and that I can withdraw at any time.	
• I agree to taking part in this study, and I agree to allowing my child take part as well.	
2. Samples: • I agree to providing my child's hair samples and understand that this data will be destroyed once it has been assessed, and all personal information will be anonymised before it is sent to the lab and written up.	
3. My data: • I understand that if this study gets published, any of mine and my child's data will be anonymised beforehand.	

Contact details:

First and last name (**print name**): ……

Email address: ……

Phone number: ……

Supplement 2. Further materials for hosting on study website

The study website will host further materials and details, including:

- The study protocol
- Information about the data collection technologies
- Data management plan (incl. data access, use and storage)
- The NU ethics review outcome (i.e. permissions required and obtained)
- Risk Considerations

NU insurance cover will be sought in parallel with the ethics approval, and once obtained details added to below:

Add insurance details here

S2: Information about the data collection technologies

More detailed information about the data collection technologies will be made openly available via the study website.

Parents considering taking part in the study will also have the opportunity to hold and examine these in person before agreeing for their child to wear any of them, and parent feedback on the devices will form part of data collection.

Devices:

m Heart
Monitor

Core device: Bittium Heart Rate Monitor

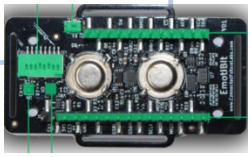
- Small and light (18 grams, 48 x 29 x 12 mm)
- Sticks on to the chest using a sensitive skin patch.
- Records the electrical signal produced by the heart beat (ECG).
- Also records movements.

Optional devices:

Emotibit:

- Worn on the arm or leg, records the pulse rate, skin conductance and temperature, and movements.
- Short battery life so would only be worn for a short time.
- Requires adult supervision while worn.
- More info: https://www.emotibit.com/

Emotibit



Napping Pants (Respiration monitor):

- A soft fabric with a built-in sensor, placed on top of the nappy, to track your child's breathing while they sleep.
- Helps us to understand the child's sleep quality.

Napping pants

Maiju Smart Jumpsuit:

- Purpose designed, with parents, a soft jumpsuit with built-in motion sensors on the arms and legs.
- Tracks movements.

Maiju Smart Jumpsuit

Hair cortisol sample:

- A small sample of hair taken by the parent
- The sample is then sent to a lab where they will measure the concentration of cortisol within it. This tells about the stress the child may have experienced.
- For more details on hair samples, see [add a further hyperlink, see next page]

Hair Sample Collection information for the researcher and parent (embedded as a further link on the website, and discussed with parents who wish to take part in this aspect of the study)

Optional background information:

Long-term measures of past physiological stress responses, as well as an unstimulated diurnal cortisol levels, can be assessed through the collection of hair samples (Russell et al., 2015; Sauvé et al., 2007). As the hair grows, cortisol is secreted into the hair shafts and can exist within the hair strand for several months after (Pragst & Balikova, 2006; Stalder et al., 2017). Specifically, as hair grows 1cm per month (Wennig, 2000), 1cm segment of hair collected from the scalp is reflective of cortisol levels in the past month, therefore a 3cm hair segment can reflect cortisol levels in the past 3 months (Stalder et al., 2017; Vanaelst et al., 2012).

Hair cortisol levels are fairly robust to external conditions, such as the number of hair washes, the hair quality and is not sensitive to changes in routine (e.g., sleep schedules and minor stressors) (see Gray et al., 2018 for review). As hair samples can be collected at any time of the day, thus posing very little burden and change to participants' routine, data collection can be scheduled around the participants liking thus proving to be useful when working with babies and toddlers with structured routines (Vanaelst et al., 2012). Supporting this, past studies using a young sample have highlighted that this measure is accepted by the children and their parents (Bates et al., 2020; Bhopal et al., 2019; Gray et al., 2018). Due to the relatively quick nature of collecting the sample and lack of burden on participants, including this measure into this study may therefore be accepted by the participants along with the additional measures.

However, as the hair must be cut as close to the scalp as possible, a gap on the child's scalp may be visible. Despite this, the amount of hair needed is approximately the diameter/thickness of a pencil and thus any visible spots will be relatively small. (Parents will be made aware that a small bald spot can occur before the hair is cut so that proper consent etc is achieved). Samples are collected from the crown of the head – this provides the most accurate and stable reflection of the child's hair cortisol concertation (Sauvé et al., 2007): deviation from this region can account for variation in cortisol levels, for example, hair samples collected from a different area on the posterior vertex in the same child, at the same time, can result in a 15.6% variation in cortisol concentration (Sauvé et al., 2007).

Information for parents on how we collect the hair samples:

The hair sample will be collected by cutting a thin piece of a child's hair – approximately a thickness of a pencil. The hair sample needs to be collected as close to the child's scalp as possible. This is to get information on the child's most recent cortisol (stress) levels. Ideally, the same researcher collects the hair samples from all the children in the study, to ensure all samples are collected in the same way. However, we will invite you to be actively involved in collecting the sample, for example cuddling your child and closely monitoring the researcher. Cutting the hair does not hurt your child or cause pain, and if you think your child seems uncomfortable with anything then we will stop – your child's happiness is the most important thing for us!

Once your child's hair sample has been cut, it will then be taped onto a paper and wrapped in aluminium foil (to keep all hair fallout together). We will store it at room temperature and send it to the lab as soon as possible.

S2: Data management

To be made available on the study website, and will be referred to as part of the consenting process.

What data will we collect?

If you take part, we will hold information collected from you and your child. We seek three types of information, but you will choose which of these you are happy to provide, or not.

BASIC INFORMATION about your family and child:

- Your contact details so that we can keep in touch with you, and
- Short questionnaires about your child's daily activities and everyday skills, using easy tick-boxes.

DIGITAL MEASURES of your child's activity, sleep and body responses:

- Your child wearing a small monitor that records their movement and heart rate.
- Your brief notes of your child's activities, on the days you choose to use the monitor at home.
- Other technologies you may choose to try out.
- Video-recordings of your child's play.

MORE IN-DEPTH INFORMATION about your child's everyday life, and about your experiences of the devices:

- You providing brief spoken comments about any of the devices and technologies you look at or may choose to try out.
- Notes by one of our researchers, from a visit to you and your child, where the researcher spends time with you. This is only if you agree, and the time and location would be chosen by you.

Most of this information is optional, and you will be able to choose which parts you want to be involved in, and which devices your child wears. If you choose to stop taking part in the study at any point, we will retain the information you have provided so far but will not collect any more or new information.

All information will be stored securely. Some information will be used for the study management only, and not be shared with anyone outside the research team at any point, now or in the future.

Some information will be further processed, to make it non-identifiable. This means removing anything that would allow you or your be identified. These non-identifiable data will then be used to answer the research questions, and may be shared with other researchers and students, and published.

<u>For all study participants we will collect:</u>

Temporarily for study management only: *Names, addresses, date of birth, video recordings*

For long term storage within the study team only: *sex, child's views on devices, core device ECG recordings, core device movement recordings (acceleration), information on the child's developmental capacity.*

For non-identifiable analysis, use and sharing: *age in months, sex, index of multiple deprivation, themes about children's views, ECG recordings, acceleration recordings, developmental capacity summary descriptions*

For all participants who wish to use the ethnographic research methods we will collect:

Temporarily for study management only: *the researcher's diary notes; parent diary notes; observations made by the researcher; video recordings and/or photos within daily life.*

For long term storage within the study team only: *A confidential, unique study ID linking the data to a study participant.*

For non-identifiable analysis, use and sharing and sharing with other researchers: *non-identifiable summary of diary information, non-identifiable summary of observations, non-identifiable video/photos*

For all participants who wear the Emotibit we will collect:

For long term storage within the study team only: *A confidential, unique study ID linking the data to a study participant.*

For non-identifiable analysis, use and sharing and sharing with other researchers: *photoplethysmogram (pulse rate) recordings, humidity and temperature recordings, accelerometer (movement) recordings, skin conductance recordings, body temperature recordings.*

For all participants who wear the respiration monitor (napping pants) we will collect:

For long term storage within the study team only: *A confidential, unique study ID linking the data to a study participant.*

For non-identifiable analysis, use and sharing and sharing with other researchers: *respiration rate, and movements (collected only during sleep), allowing us to assess sleep quality.*

For all participants who wear the Maiju Suit we will collect:

For long term storage within the study team only: *A confidential, unique study ID linking the data to a study participant.*

For non-identifiable analysis, use and sharing and sharing with other researchers: *detailed acceleration and gyroscope data that allows identification of movement types (collected only for a short period of time).*

For all participants who have hair sample taken we will collect:

For long term storage within the study team only: *A confidential, unique study ID linking the data to a study participant.*

For non-identifiable analysis, use and sharing and sharing with other researchers: *concentration of cortisol in the hair sample.*

The full data management plan can be viewed here: https://newcastle.sharepoint.com/:w:/r/sites/WEARable/Shared%20Documents/General/3.%20Protocol/Data_Management_Plan.docx?d=wa0c6413e9bb5485cafb3a532cb1ee1ac&csf=1&web=1&e=aatpXv

S2: Risk Considerations

Risk Assessment Form			
This risk assessment form should be completed electronically and approved and signed by the appropriate responsible person: principal investigator (PI), module leader, tutor, or dissertation mentor. Guidance on completing this form is provided on the University Safety Office website and in the HSE guidance Five Steps to Risk Assessment, which can be downloaded from the HSE website or USO website. It is the responsibility of the person in charge of the fieldwork that this risk assessment is made available to all participants of the fieldwork			
Title of project and/or module: Physical activity, sleep and physiological health in young children: A feasibility and acceptability pilot study			
Persons conducting fieldwork (PI or student): Dr Christopher Thornton, Dr Niina Kolehmainen, Emily Hunter Other people involved in this fieldwork: (If needed attach separate sheet): Christopher Eggett, Abigail Collins Date(s) of fieldwork: September 2022 - September 2023 Location(s) of fieldwork: NUPHSI, and participant's homes around Newcastle upon Tyne			
Field activity outline: (brief synopsis): Data collection in dry lab (observations); followed by travelling to participants homes to perform ethnographic research within the home of research participants. The researcher will spend several hours (no more than 4) with the participants, observing and recording their everyday activities. A feedback session with parents with two researchers.			
Hazards, Risks and Controls *It is important to understand the difference between hazard and risk. The hazard of a substance/activity/condition is the intrinsic property of the substance/activity/condition to cause harm. The risk in relation to exposure to a hazard means the likelihood that the potential for harm will be expressed under the conditions of use and the severity of that harm. The main purpose of your risk assessment is to identify the hazards, decide who is at risk (Bear in mind that as a result of your activities, members of the public might be at risk), assess the level of risks to people, and decide on suitable controls to ensure that the work can be done safely.*			
List the potential Hazards. Assess the level of risk (E = Extreme: needs immediate action, H = High, M = Moderate, L = Low, N = Negligible). Outline the control measures put in place ('so far as is reasonably practicable') to reduce the risk. Then assess the level of risk with the control measures in place.			
Potential hazard	Level of risk	Control measures to reduce risk	Reduced level of risk
Observations in lab	L	Child-friendly set up, with focus on observation through play. Parent is with the child at all times, and actively inputs and influences the process – ensuring the child is happy and comfortable. Two researchers present for each observation, including a senior researcher with significant clinical experience of working with children.	N

Travel Travelling via own car – car breaks down/accidents	L	Ensure car is checked (e.g., condition of tires, level of fuel) before journey. Taxi number at hand.	N
Getting lost on the way to the location	L	We will check with participant that address is correct, and use google maps and check the journey route beforehand.	N
Being alone when traveling and meeting participants	M	Parent is already known to the research team from the observation (above). Established Buddy process will be followed, with a second researcher (Thornton or Kolehmainen) in close contact with the ethnographic researcher (Hunter) throughout the day of research. A portable phone charger will ensure phone contact will not be disrupted by battery failing.	L
Dealing with other people in the community Not being recognised as the researcher	L	Will wear staff ID badge to confirm identity and carry DBS check to show participants if required.	L
Health Catching or passing on COVID-19	M	Keeping up to date with the guidelines; not visiting families when feeling at all unwell (either self, or the family); keeping good hygiene (hands, social distance); being mindful of wearing a mask but judgement for this to be used by the researcher in communication with the family.	L
Location Specific Car or personal belongings getting lost or stolen	L	Will park car a short walking distance from participants house. Not leave materials visible in the car. Carefully considering the safety of the area when parking, and not parking in isolated or dark areas.	L
Activity Specific Hair cortisol sample	L	We will follow an existing, already NU Ethics approved, protocol that is currently being used in another study of young children, at home settings, without problems.	L
Feedback to parents could be upsetting or misunderstood	M	The feedback is carefully planned out, using best practice principles and the senior researcher's experience of similar feedback situations in this population. The focus will be on sharing factual information and data in a way that is accessible for the parents, to make the study meaningful for them. Emphasis will be on facilitating parents to ask questions. No statements or opinions will be made about the child's	L

		development, capabilities or relationship to any population norms.	
Equipment Specific The sensor devices could present a choking hazard to the children	L L	The Bittium and Movesense (for MAIJU suit or NAPPING pants) sensors are sealed within a case and have been designed for use with young children. The emotibit will be used under the direct supervision of a member of the research team only. The device will be contained within a plastic case, preventing access to any internal parts. The memory card slot of the emotibit will be sealed using electrical tape to prevent removal of the memory card.	L L
Oher hazards N/A			

Personal Protective Equipment (PPE) Indicate on the list below which PPE is required for this fieldwork: Mobile phone, portable charger.

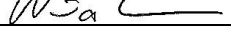
Risk Control Measures Indicate the standard risk control measures needed:
Adequate drinking water, Work with support from the team and/or buddy, Emergency details at hand, carry a mobile phone, Insurance cover & documents

Other control measures: N/A

Training: Buddy process.

Emergency plan:
Despite all preparations and no matter how careful you are, accidents can happen. Indicate procedures to follow in an emergency (who do you contact, where do you go).

Contacts	
Accommodation	N/A
Emergency services	999 – emergency 111 – non emergency
Nearest hospital	RVI, Queen Victoria Road, Newcastle upon Tyne, NE1 4LP, +44 191 233 6161
Police	999 – emergency 101 – Non emergency
British embassy	N/A
Insurance contact & policy no.	N/A
Other	
University emergency telephone number	+44 (0)191 222 6666

Assessor Lead Day-to-Day Researcher	**Name** Christopher Thornton	**Signature** 	**Date** 01/08/2022
Approval PI	**Name** Niina Kolehmainen	**Signature** 	**Date** 15/08/2022

Supplement 3. Feedback to parents

The feedback sessions with parents will be relaxed and informal. We will work at the pace set by the parents, and the aim is to enable parents to have a better sense of the data that has been collected from them, and how that will be further used to answer the research questions.

The following list provides an indication of the topics that may be covered, however it is not a check list and will not be used as such.

- Thanking the parents and child for their participation.
- Recap on the aims, and data collected from that family.
- Share examples of raw and processed data with the family – including easily accessible examples.
- If possible, share some early examples of cumulative / aggregate data (e.g. examples of themes emerging from parent feedback).
- Reminder of how the data will be stored and shared, including concrete examples from previous similar studies.
- Open questions to explore parents' experiences of the study, and any further feedback and questions they may have.

Supplement 4. General Information Questionnaire

Sample background questionnaire. The other questionnaires are computerised online questionnaires and it is not possible to share examples of them in paper format.

These questions provide the research team general information about who is taking part in the study. The information will be kept separate from your contact details, including your name. It will only be used to describe the study participants, at a general level.

Q1: Is your child: [*circle the relevant option*] a Boy a Girl Other
Q2: What is your child's date of birth? _____/_____/_____
Q3: What language(s) does your child speak at home? _____
Q4: Who is your child's main carer? [*circle the relevant option*] Mother Father Grandparent Other
Q5: What is the main carer's highest educational qualification? _____
Q6: Does your child: Walk (with or without support)? Yes No Talk words? Yes No Have a diagnosed health condition? Yes No If yes, if you are happy to share what it is, please write here: _____
Q7: What are you most proud about your child?
Q8: What do you wish your child could do they are not doing at the moment?
Q9: What post code does your child live in? _____ *We will use your child's post code to develop general description of the participating children's environments. The post code will <u>not</u> be shared with anyone and not be reported in any publications.*

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