

Protocol



Short Title: BabySMART

Study Title: BABY SMART (Study of **M**assage therapy, sleep **A**nd neurodevelop**Ment**)

Project Title: ENRICH - INFANT Baby Enrichment Research Programme

Protocol Sponsor Number: GB02/17UCC
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Principal Investigator: Professor Geraldine Boylan

Sponsor: University College Cork,
College Road,
Cork,
Ireland

Recruitment Site(s): Multicentre: International

Protocol

BABY SMART (Study of Massage therapy, sleep And neurodevelopment)

Chief Investigator: Prof Geraldine Boylan,
Professor of Neonatal Physiology
Irish Centre for Fetal and Neonatal Translational Research,
Cork University Maternity Hospital,
Wilton,
Cork
Ireland

Sponsor: Dr Muiris Dowling
Office of Vice President of Research and Innovation
University College Cork

Recruitment Sites and Local Principal Investigators

**Cork University Maternity Hospital
(CUMH) & Cork University Hospital
(CUH)**
Wilton,
Cork
Ireland

**University College London - Institute of Child
Health
(UCL-ICH)**
30 Guilford Street
London WC1N 1EH
United Kingdom

Principal Investigators
Prof Eugene Dempsey,
Prof of Paediatrics and Consultant
Neonatologist,
Cork University Maternity Hospital

Dr Deirdre Murray,
Senior Lecturer and Consultant Pediatrician,
Department of Pediatrics and Child Health
and INFANT, UCC
Cork University Hospital

Principal Investigator
Dr Ronit Pressler
Consultant in Clinical
Neurophysiology/Honorary Reader
Great Ormond Street Hospital for Sick
Children
University College London - Institute of Child
Health

Additional Project Staff

Project Manager

Ms Darina Sheehan,
INFANT Research Centre
University College Cork,
Ireland

ENRICH Physiotherapist

Ms Anne Marie Cronin
INFANT Research Centre
University College Cork,
Ireland

ENRICH Research Nurse

Ms Claire O'Halloran
INFANT Research Centre
University College Cork,
Ireland

ENRICH Clinical Neurophysiologist

Dr Sean Mathieson
INFANT Research Centre
University College Cork,
Ireland

INFANT Biostatistician

Dr Vicki Livingstone
INFANT Research Centre
University College Cork,
Ireland

INFANT Study Monitor/Quality Control

Ms Jackie O'Leary
Department of Paediatrics & Child Health
University College Cork,
Ireland
Contact point(s) in case of emergencies 00 353 86 8116363 (Mobile)

Study Medical Experts

Prof Eugene Dempsey,
Prof of Paediatrics and Consultant
Neonatologist,
Cork University Maternity Hospital

Dr Deirdre Murray,
Senior Lecturer and Consultant Pediatrician,
Department of Pediatrics and Child Health
and INFANT, UCC
Cork University Hospital

1 Background

It is well known that sleep is essential for brain development (3) and learning (4). Infants require extensive sleep for development of the hippocampus, pons, brainstem, and midbrain and for optimizing physical growth. It is also essential for *brain plasticity*; the genetically determined ability of the infant brain to change its structure and function in response to the environment. Studies in young animals have shown that sleep deprivation leads to increased programmed cell death, smaller brain size, and loss of brain plasticity, all of which have negative long-term impact on behaviour and learning ability (5-7).

Infant massage, a form of systematic tactile stimulation by human hands, improves sleep hygiene. Very little is known about how massage influences early brain development but it is certainly linked to the theory of environmental enrichment, which has been well established in animal models. (8-10).

2 Aims of the BabySMART project

The aim of this project is to optimise the infant's sensory experience through a multi-sensory enrichment programme, including massage (a massage utilising a scented lotion before sleep each day), to encourage more structured sleep and ultimately show improved developmental and cognitive outcomes.

3 Hypothesis

The BabySMART study will examine the effect of a structured sensory enrichment programme including massage, delivered by parents according to a structured programme following training, on both the quality and quantity of sleep and on subsequent neurodevelopment

4 Significance of the question

It is well known that sleep is essential for brain development and maturation. Studies have shown that sleep-deprived young animals have smaller brains with loss of brain plasticity, which leads to diminished learning and adverse long-term behavioural effects. It is also established that infant massage improves sleep hygiene and is linked to the theory of environmental enrichment, which promotes brain development. Brain development during the first years of life depends on the quality of stimulation in the infant's environment. Early child development is a life-long determinant of health and well-being. There are significant societal and economic benefits from optimal infant cognitive development (2).

5 Trial Objectives and Purpose

Primary objective

To assess the effect of a structured sensory enrichment programme on Infant sleep using qualitative and quantitative measures.

Secondary objective

To assess the effect of a structured sensory enrichment programme on neuro-development as assessed by a standardised neurodevelopmental assessment at approx. 4 months and approx. 18 months of age.

6 Description of protocol methodology

6.1 Type of Trial

We will undertake a multi-centre, unblinded, randomised, controlled study to evaluate whether a multi-sensory enrichment programme in the first 4 months of life will improve sleep architecture and neurodevelopment in healthy infants.

We do not interpret this study as a clinical trial, as defined by the Control of Clinical Trials Act, 1987 and 1990.

6.2 Subjects

A total of 200 full term healthy infants will be studied. Recruitment will take place at CUMH and UCL-ICH London.

Inclusion criteria for participant selection are:

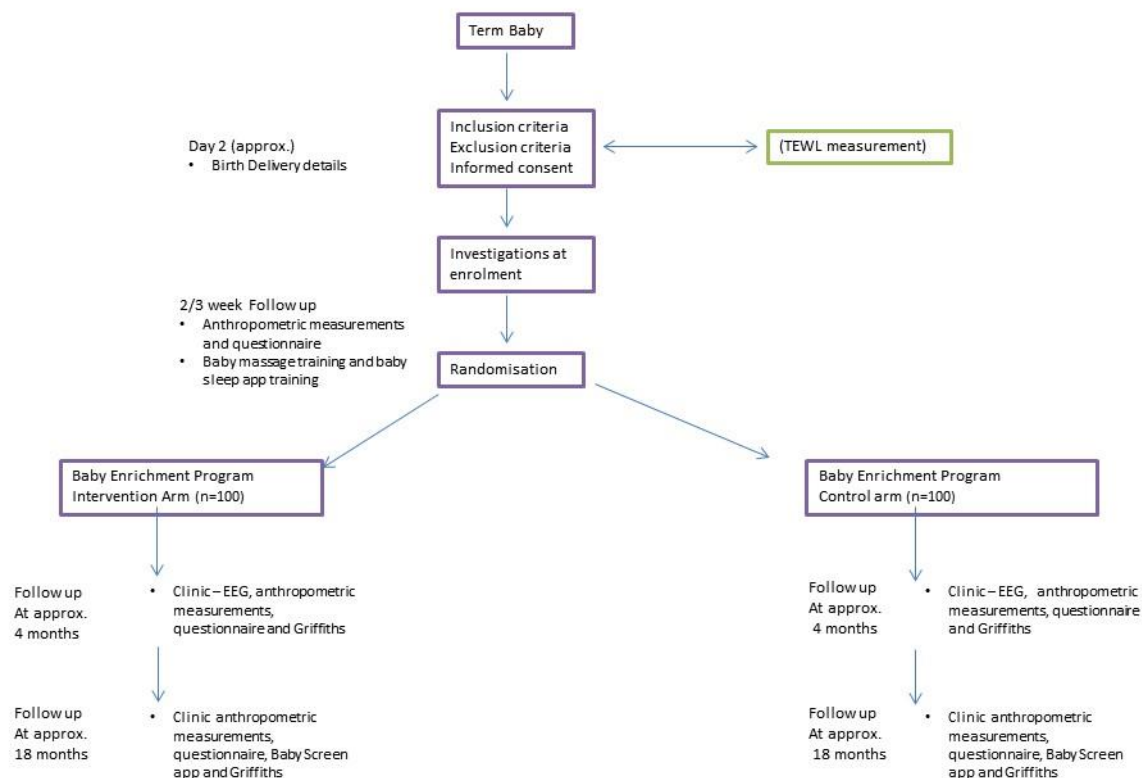
- Infants born > 37 weeks gestation
- Single births
- Not requiring admission to the Neonatal Unit
- Healthy infants without suspected congenital or metabolic anomalies

Exclusion criteria for participant selection are:

- Infants born < 37 weeks gestation
- Multiple births

- Severe metabolic or genetic anomaly that would require ongoing specialist care in the infancy period.

Admission to the Neonatal Unit.6.2.1 Figure 1 Flow chart design of study



6.3 Contact with study participants

Mothers will be approached post- delivery, at the bedside, usually within 48 hours, in the wards in CUMH, they will be informed about the study and given a study leaflet to read. If they decide to participate in the study the consent form will be signed and the next steps will be explained to the parents.

Once the day of consent assessment is complete, ideally day 2 after birth, parents will be informed that the next appointment will be in approximately 2 - 3 weeks and that a member of the BabySMART team will contact them to schedule this appointment and randomisation will occur at this follow up visit.

Phone Call for follow on appointments in BabySMART

1. All postnatal appointments are to be made 1-2 weeks prior to scheduled follow-up.
2. Remind mothers of the BabySMART study; ask how baby has been getting on.
3. Schedule an appointment for follow up appointment in the INFANT research centre in the CUH (approx. 4 months and approx. 18 months).
4. Again, tell them we will send a reminder text the day before and if there are any problems to contact the study team and that an alternative appointment can be made.

Reminder texts

- **For the approx. 2 week, 4 month and 18 month visit texts**

A reminder of your appointment with the BabySMART Study tomorrow in the INFANT Research Centre in CUH. Thanks from BabySMART

7 List of BabySMART Procedures

7.1 Anthropometry (2 weeks, 4 month and 18 month time points)

Weight, height (supine length) and head circumference will be measured using a standard technique and equipment at the visits that will take place at approximately 2 weeks, 4 months and 18 months. Measurements will be taken according to the relevant INFANT Work Instructions. The same measuring equipment will be used for the duration of the study and staff will be both familiar with the technique and equipment before completing a measurement.

7.1.1 Trans-epidermal water loss measurement (TEWL) (2 day, and 4 month time points)

Trans-epidermal water loss (TEWL) measurement will be taken using standard technique and equipment (Delfin Vapometer) at the visits occurring on approximately Day 2 and 4 months. Parents will be asked not to apply emollients on the morning of the visit and any non-compliance will be documented. Three measures will be taken and the average reading recorded in the eCRF.

7.2 EEG measurements (4 month time points)

A sleep video/ EEG will be performed on babies recruited into the BabySMART study at approximately 4 months of age (conceptual). Parents will be invited to bring their child to the baby sleep lab, INFANT Research Centre in the CUH for this appointment. The timing of this should be coordinated so the recording commences following a feed around the time of the baby's longest daytime nap. The recording will last for the duration of the baby's sleep.

Recording parameters

The EEG recording will be made using the study EEG machine and follow the INFANT Sleep EEG Work Instructions which were devised according to the American Academy of Sleep Medicine (AASM) (10). Each recording will be made using disposable electrodes and will include respiration, Electrooculography (EOG), Electrocardiography (ECG) and Electromyography (EMG) measurements for qualification of sleep states.

EOG is a technique for measuring/ recording eye movements. Pairs of electrodes are typically placed either above and below the eye or to the left and right of the eye and the recorded potential is a measure of the eye's position.

ECG is the process of recording the electrical activity of the heart over a period of time using electrodes placed on the skin. These electrodes detect the tiny electrical changes on the skin that arise during each heartbeat from the heart muscle. These electrodes will be placed on the left and right deltoid muscle of the arm.

EMG is used to measure muscle movement and two electrodes will be applied approximately 2 cm to the left of the midline and 2cm to the right of the midline, with both electrodes approx. 2cm below the inferior edge of the mandible.

A specialized respiration electrode will be used to measure respiration rate. All recordings will be assigned a study ID number and pseudo anonymised. Any incident findings will be followed-up clinically.

7.3 Sensory enrichment programme including infant massage

A total of 200 full term healthy infants will be recruited. Recruitment will take place at CUMH and UCL-ICH London. Parents will be invited to provide proxy consent for their infant to participate and also for their own participation in the BabySMART study.

Once Day 2 screening assessment is complete, parents will be informed that the next appointment will be in approximately 2 - 3 weeks and that a member of the BabySMART team will contact them to schedule this appointment. Randomisation will occur at this visit. Participants will be randomised to either a structured sensory enrichment programme including infant massage (intervention arm) or to the control arm.

The massage will be applied according to IAIM (International Association of Infant Massage). Created in 1976 by Vimala McClure, it is the first global organisation with a professional programme which is run in several countries around the world, due to its proven benefits. The purpose of IAIM is to create a nurturing touch and communication through training, education and research so that parents, caregivers and children are loved, valued and respected throughout the world community.

At the 2 week visit parents will be provided with training in infant massage by an instructor who has completed a Baby Massage Ireland trainer course. The massage should be carried out daily until the 4 month visit. Massage training will be completed on-site in the INFANT Research Centre in the new Paediatric unit in the CUH and the JOHNSON'S® HEAD-TO-TOE® extra moisturizing baby cream will be supplied at these appointments

Mothers will be informed about the enrichment programme which will include the benefits of baby massage, infant cues, duration of application, points of care for application and application technique at this stage. The technique of massage application will be shown to the mother by the researcher using a model baby (doll).

Mothers will be asked to apply the massage on their own baby as instructed and they will be observed to determine whether they applied the massage correctly or not. Training will be reinforced both at the training session and by the provision of a training DVD which will be provided to parents.

Baby massage education will also be given at drop in classes where a review of the strokes will be undertaken. Each parent's application of baby massage will be observed and evaluated for correct

technique. Extra JOHNSON'S® HEAD-TO-TOE® extra moisturizing baby cream will be supplied at these classes. Parents will be encouraged to massage their babies a minimum of 3 x 15-minute sessions including a minimum of 2 of the 6 areas to be massaged, every day for the first 4 months of life.

The researcher will follow HSE protocols to help women improve the care of their baby, or other questions that may arise; sleep positions, weaning, vaccines, feeding, bathing.

7.1.5 Neurodevelopment assessments (4 month and 18 month time points approximately)

All participants in the study will receive a standardised developmental assessment at 4 months and 18 months of age approximately. The Griffiths III Mental Development Scales published in 2016, measures development trends which are significant for intelligence, or indicative of functional mental growth in babies and young children. The new Griffiths III measures maturation from 0 to 5 years 11 months of age. Griffiths III is a restricted test that is available only to the holders of an ARICD Certificate of Registration as User. Griffiths training courses are open to paediatricians and psychologists.

Allied Health Professionals who are

- 1) part of a Child Development Team, or
- 2) actively involved in research or monitoring, and
- 3) can be supervised by an experienced Griffiths user, may also apply.

Neurodevelopment assessment using the Griffiths III will be performed by a trained member of the INFANT team and will be conducted using the recognised Griffiths kit, manual, and other related material. Assessments will take place in the Early Life Lab, INFANT Discovery Platform in CUH or if required the INFANT researcher will travel to the infant's home.

The new Griffiths III provides an overall measure of a child's development, as well as an individual profile of strengths and needs across five areas:

- A: Foundations of Learning
- B: Language and Communication
- C: Eye and Hand Coordination
- D: Personal – Social - Emotional
- E: Gross Motor

Any worrying or incidental findings will be referred for follow up along the relevant clinical pathway.

7.4 Questionnaires (2 week, 4 month and 18 month approximate time points)

7.4.1 Socio-demographic data

For an example please see Appendix

7.4.2 Baby's household and health

For an example please see Appendix

7.4.3 Mothers postnatal depression questionnaire & parental attachment style – approximately 4 month time point only

The survey contains questionnaires that are directed at screening for postnatal depression, identifying the attachment type of the parent and evaluating the growing relationship between the mother and infant.

The Maternal Postnatal Attachment Theory questionnaire (MPAS; Condon & Corkindale, 1998) captures different sorts of emotional reactions parents have when caring for young babies. Of particular interest to this study is the mother's attachment style to the infant. (Please see Appendix) Postnatal depression scores will be measured through the Edinburgh Postnatal Depression Scale (EDPS; Cox, Holden & Sagovsky, 1987). This questionnaire will be utilized as a screening tool for postnatal depression. (Please see Appendix).

It is estimated that up to 1 in 7 new mothers will experience postnatal depression (PND) (Health Service Executive, 2008). It is therefore expected that a similar percentage of mothers in this study will have escalated scores on the EDPS. It is imperative that a referral pathway be identified to ensure the women obtain a comprehensive follow up if their scores indicate they are at risk of PND. Mothers who have an escalated score on the EDPS (score >10) or who have an escalated score in the anxiety subscale of the EDPS (scores > 6) or who have answered positively to the suicidal risk question (Scores > 0) will all receive follow up. As recommended by the EDPS any participant with an escalated score will be given the EDPS to complete again after two weeks. Participants who remain in the moderate range (score 10-13) after completing the EDPS for the second time will be strongly advised to consent to a GP referral, while participants exceeding this threshold and scoring in the high risk threshold (score 13-30) will be automatically referred to their GP.

7.5 MiChild Mobile Application

MiChild is a mobile application which is to be used by registered users only for the capture, storage and analysis of sleep and feeding. The aim of this app is to provide researchers working on the BabySMART study with a view of key infant data from birth to 4 months. The application is not mandatory and the parents can choose to record the information in a paper format in the diary that has been designed for the study. MiChild will provide a data capture tool where parents can capture in real time details on infant sleep, adherence and acceptance of the sensory enrichment programme and limited feeding data. The data inputted by parents will be available to them in an aggregated view allowing them to review weekly sleep and feeding.

This secure, multi-platform (Android & iOS) mobile solution will provide parents/guardians with the ability to capture an accurate and real-time view of their infant's sleep and feeding from birth. As well as the above, the application will also allow communication between parents and BabySMART research staff via a messaging option.

This application will be available through the apple app store and google play store. The application will only be accessible to parents who have a registered account created by research staff working on the BabySMART Study.

Registered users of the app will be created by research staff with the necessary privileges through an administrative application. These registered users will be provided with a random password by the BabySMART research staff at time of registration. This password will be stored in the database encrypted using industry standard Advanced Encryption Standard – Cipher Block Chaining (AES-CBC) which will have a 256-bit key for encryption. The registered user of the app will have to enter a “MiChild” user ID which is unique to the app and is created by the BabySMART research staff. This ID combined with their password allows a user's access to the application. At any stage throughout the use of the application, clinical staff can deactivate an account and therefore render the app un-usable by the users.

All data will be stored in University College Cork, on University College Cork servers. These servers will have restricted access to INFANT IT personnel only. All data on these servers will have restricted access insofar as it will be restricted to BabySMART research staff only so as to protect patient confidentiality.

All data will be stored within University College Cork. All data being transferred to and from University College Cork will be encrypted using secure SSL whilst being transferred and identifiable pieces of data will be encrypted at rest. Data at rest will be encrypted using industry standard Advanced Encryption Standard – Cipher Block Chaining (AES-CBC) which will have a 256-bit key for encryption. Please see Appendix E for screen shots of this mobile application.

8 Confidentiality

Data protection and privacy

All national and local legal requirements regarding data protection will be adhered to. Pseudoanonymity of patient data is assured by means of the unique study ID number allocated on enrolment. Throughout the study, participants will be identified by this study ID number. At each site, the Principal Investigator will hold a hard copy list linking the study ID to patient details. This list will be kept in a locked filing cabinet. If the patient name, initials or year of birth appear on a document (e.g. laboratory report), that has to be transferred within the notification duties, these data will be obliterated before a copy of the document is transferred. Participants will be informed that all study data will be stored on a computer and handled in strictest confidence. Participants will also be informed that monitors, representatives of the sponsor, the Ethics Committee may inspect their medical records to verify the information collected, and that all personal information made available for inspection will be handled in strictest confidence and in accordance with legal data protection requirements.

9 Governance

The conduct of the BabySMART study will be overseen by the ENRICH Steering Committee, which consists of one nominated representative from each party in the Consortium. All major decisions regarding the ENRICH project and its data must be approved by this Committee. All members of the Steering Committee will make yearly declarations of conflict of interest and these will be posted on the ENRICH website.

10 Insurance

The Study is covered by University College Cork, Clinical Trial Indemnity Insurance and was finalised by the Office of Corporate and Legal Affairs (OCLA).

11 Ethical Committee Review

The Protocol will be reviewed and approved by the appropriate Ethics Committee(s) in each country. All investigation personnel will implement the Protocol with full respect and compliance to the legal and ethical European / institutional requirements and codes of practices.

12 Amendments to the Protocol

All amendments to the Protocol, Parent Information Leaflet (PIL) and Informed Consent Form (ICF) shall be agreed between the Sponsor and the Principal Investigator and will be recorded with a justification for the amendments. All Protocol, PIL and ICF amendments will be submitted and approved by the relevant Ethics Committee(s) as required before implementation.

13 Deviations from the Protocol

The Investigator is not allowed to deviate from the Protocol unless under emergency circumstances, to protect the rights, safety and well-being of participants. The deviation may proceed without prior approval of the Sponsor and the EC. All deviations shall be documented and reported to the sponsor, and the EC as soon as possible. All deviations from the Protocol shall be recorded together with an explanation for the deviation. Deviations shall be reported to the Sponsor who is responsible for analysing them and assessing their significance. Deviations should be reviewed to determine the need to amend the Protocol, implement corrective/preventive action (CAPA) or to terminate the study. A master deviation tracking log will be maintained for the duration of the study outlining each deviation, any CAPA implemented and date of resolution.

14 Withdrawal of Participants from the study

Participation is voluntary and participants may withdraw from the study at any time and for any reason. All withdrawals will be documented and the reasons recorded where possible.

15 Adverse Event Reporting

The following Johnson & Johnson Consumer Services EAME Ltd (JJCSEL) products will be provided to parents participating in BabySMART.

BabySMART research personnel will be responsible for collecting and reporting any information in or coming into its possession or control for the PRODUCTS regardless of source, relating to an Undesirable Effect (UE), Special Situation or an UE associated with a Product Quality Complaint (UEPQC) and Incomplete Cases, in a format as agreed upon with Johnson & Johnson Consumer Services EAME Ltd (JJCSEL).

This information and any Incomplete Cases should be reported immediately, but in no case later than twenty-four (24) hours from first becoming known to BabySMART personnel. The minimal information required for notification is a suspect PRODUCT and an event. BabySMART personnel will collaborate to identify any missing safety information, including, but not limited to, completeness of case identification numbers, in case of discrepancies, to ensure receipt of all collected safety information by JJCSEL

A tracking system will be established and maintained for the collection, recording and collation of safety information for the PRODUCT. A summary of all identified UE, Special Situation, and UEPQC, must be maintained and reported as outlined in the Safety Reporting scope of work.

15.1 Definitions

“Product Quality Complaint” (PQC) Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a product after it is released for distribution.

PRODUCTS

JOHNSON’S® HEAD-TO-TOE® extra moisturizing baby wash

JOHNSON’S® HEAD-TO-TOE® extra moisturizing baby cream

“Special Situation”: Occurrences or reports that may not contain an adverse event, which must still be collected and reported in order to meet regulatory safety reporting requirements and JJCSEL Company policies:

- Overdose of Product,
- Pregnancy exposure (maternal and paternal),
- Exposure to the Product from breastfeeding,
- Suspected abuse/misuse of the Product,
- Inadvertent or accidental exposure to the Product (including occupational exposure),
- Any failure of expected pharmacological or medical device action (i.e. lack of effect) of the Product,
- Unexpected therapeutic or clinical benefit from use of the Product,
- Medication error involving the Product with or without patient/consumer exposure to the Product, (e.g. name confusion) OR that caused an unintended effect or could cause an intended effect (e.g. adult medicine given to a young child),

- Suspected transmission of an infectious agent via Product,
- Expired drug use and falsified medicine
- Off-label use - situations where the Product is intentionally used for a medical purpose not in accordance with the authorized product information

"Undesirable Effect" (UE) shall mean an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product.

15.2 Follow Up

JJSEL will be responsible to follow up on safety information. In the event the BabySMART study team receives follow up information this will be forwarded in the same timelines and mechanism as initial information noted above and will include the receipt date for the follow-up information.

16 Bibliography

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17 Approval and Agreement to the Protocol

Signatures

The Sponsor, Chief Investigator and Principal Investigator, United Kingdom, have discussed this protocol. All have agreed to perform the clinical study as written and to abide by this protocol except in case of medical emergency or where departures from it are mutually agreed in writing.

Chief Investigator

Professor Geraldine Boylan, INFANT Research Centre, University College Cork, Ireland

Signature

Date:

Principal Investigator – United Kingdom

Dr Ronit Pressler, University College London, Institute of Child Health United Kingdom

Signature

Date:

Sponsor

Dr Muiris Dowling, University College Cork, College Road, Cork, Ireland

Signature

Date:

APPENDIX

Baby SMART – 2 week questionnaire

Socio-demographics

1. Marital Status
- | | |
|--|--------------------------|
| Single | <input type="checkbox"/> |
| Married/Living as married | <input type="checkbox"/> |
| In a relationship (not living together) | <input type="checkbox"/> |
| Separated /Divorced | <input type="checkbox"/> |
| Widowed | <input type="checkbox"/> |
| In a registered same sex civil partnership | <input type="checkbox"/> |

2. Mother's ethnicity

3. Father's ethnicity

(eg. White Irish, White non Irish, Black African/American, South Asian etc.)

4. Mother's nationality

5. Father's nationality

(eg. Irish, British, Polish, French, African, Asian, American etc.)

6. What is your highest level of education (mother)?

- | | |
|---|--------------------------|
| No formal education | <input type="checkbox"/> |
| Primary school | <input type="checkbox"/> |
| Secondary school - Junior/Inter Certificate | <input type="checkbox"/> |
| Secondary school - Leaving Certificate | <input type="checkbox"/> |
| Third level - Certificate | <input type="checkbox"/> |
| Third level - Diploma | <input type="checkbox"/> |
| Third level - Degree | <input type="checkbox"/> |
| Third level - Higher/Graduate Diploma | <input type="checkbox"/> |
| Third level - Masters | <input type="checkbox"/> |
| Third level – Phd | <input type="checkbox"/> |
| Other, please specify | <input type="checkbox"/> |

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7. Current job situation

Full time work

☐

Part time work

☐

Student

☐

Homemaker

☐

Unemployed

☐

Sickness beneficiary

☐

Other

☐

8. Maternal Occupation

--

(Please give specific details of your occupation; also if you have been unemployed for less than 6 months please give title of previous job)

9. Current living situation (please tick all that apply)

Your Spouse/Partner	<input type="checkbox"/>
Your Parents/Your Spouse/Partner's Parents	<input type="checkbox"/>
Friends	<input type="checkbox"/>
Housemates	<input type="checkbox"/>
Alone	<input type="checkbox"/>
Other	<input type="checkbox"/>
<input type="text"/>	

10. Type of accommodation	Own house/flat mortgage free	<input type="checkbox"/>
	Own house/flat with mortgage	<input type="checkbox"/>
	Private rental	<input type="checkbox"/>
	Gov. /Council rental	<input type="checkbox"/>
	Hostel/boardings house	<input type="checkbox"/>
	Garage	<input type="checkbox"/>
	Mobile Home/Caravan	<input type="checkbox"/>
	Part own/part rent house/apartment	<input type="checkbox"/>
	Other	<input type="checkbox"/>
	<input type="text"/>	

11. Parents combined net income (after deductions of tax and PRSI) Please tick one

<i>Per Week</i>	<i>Per Month Per</i>	<i>Year Category</i>	
Under €230.....	Under €1,000.....	Under €12,000	<input type="checkbox"/>
€231 to under €350.....	€1,001 to under €1,500.....	€12,001 to under €18,000	<input type="checkbox"/>
€351 to under €460.....	€1,501 to under €2,000.....	€18,001 to under €24,000	<input type="checkbox"/>
€461 to under €575.....	€2,001 to under €2,500.....	€24,001 to under €30,000	<input type="checkbox"/>
€576 to under €800.....	€2,501 to under €3,500.....	€30,001 to under €42,000	<input type="checkbox"/>
€801 to under €925.....	€3,501 to under €4,000.....	€42,001 to under €48,000	<input type="checkbox"/>
€926 to under €1,150.....	€4,001 to under €5,000.....	€48,001 to under €60,000	<input type="checkbox"/>
€1,151 to under €1,500.....	€5,001 to under €6,500.....	€60,001 to under €78,000	<input type="checkbox"/>
€1,501 to under €1,850.....	€6,501 to under €8,000.....	€78,001 to under €96,000	<input type="checkbox"/>
€1,851 or more	€8,001 or more	€96,001 or more	<input type="checkbox"/>

Prefer not to say	<input type="checkbox"/>
Don't Know	<input type="checkbox"/>

12. Number of individuals supported by this income	Adults	<input type="text"/>
	Children	<input type="text"/>

Environment

13. In what suburb or town do you live?

14. In what type of area do you live?
 (population<2000) ☐ Urban ☐ Rural

15. If you live in a rural area, do you live on a: ☐ Farm
☐ Open countryside
☐ Small town/village

16. How many people live in your house hold?
 Number of adults
 Number of children (<18years old)

17. Do you currently smoke? Yes ☐ No ☐ Yes e-cigarettes only ☐

18. If Yes, how often do you smoke?

Daily/Almost Daily
 A few times per week
 Once a week
 Less than once a week

19. How many, on average each day?

20. Do you allow smoking in your house?

No
 Yes, occasionally
 Yes, regularly
 Yes, e-cigarettes only

21. Is your baby exposed to smoking outside the home (eg. grandparents?)

No
 Yes, occasionally
 Yes, regularly
 Yes, e-cigarettes only

22. Where does your baby usually sleep?

Cot in your bedroom
 Cot in their own bedroom
 We share a bed

23. Does your baby ever sleep in bed with you? Yes ☐ No ☐

24. If **yes**, is it for the
 Whole night ☐
 Part of the night ☐

25. If **yes**, how often does this occur
 Every night ☐
 4-6 times per week ☐
 2-3 times per week ☐
 Once a week ☐
 Rarely ☐

26. How often do you think a new-born baby should sleep in a 24 hour period?
 hours

27. Where do you seek advice regarding your new-borns sleeping and feeding habits (tick all that apply)?

Books ☐
 Internet ☐
 Parents/Grandparents ☐
 Paediatrician/GP ☐
 Friends ☐
 Other ☐

28. Do you follow any 'Mummy Bloggers'?

Yes ☐
 No ☐

29. If Yes, who?

30. How often do you bath your baby?

Once a week ☐
 2-3 times a week ☐

4-6 times a week ☐
 Daily ☐
 Other, please specify ☐

31. What do you use in the bath?

Please specify product name and brand

32. How often do you moisturise your baby

Never ☐
 Occasionally ☐
 Once a week ☐
 2-3 times a week ☐
 Daily/Almost daily ☐
 Several times a day ☐

33. What do you use to moisturise your baby's skin?

Please specify product name and brand

Feeding

34. How are you feeding your baby?

Breast fed ☐
 Infant Formula ☐
 Both ☐

35. How many feeds do they get on average in 24 hours?

Breast-milk ☐
 Infant formula milk ☐

36. Is your baby fed on a regular schedule eg. every 4 hours?

Yes, always ☐
 Yes, try to ☐
 No, fed on demand ☐

37. Does your baby use a soother/dummy?

Yes, regularly ☐
 Yes, occasionally ☐
 No ☐

Baby's Health

38. Has your baby been unwell or needed to visit your GP (since leaving hospital)?

Yes ☐
 No ☐

39. Did your baby require any treatment or follow up (since birth)?

☐

Yes
 No ☐

40. If Yes, please give details ☐

Mother's health

41. Were you prescribed any medication during your pregnancy?

Yes ☐

No ☐

42. If YES, what were you prescribed?

43. If YES, how long did you have to take it for?

Days

Weeks

Mother's Quality of Life

We would like for you to answer a few questions about your current health state.

Please indicate which statements best describe your own health state today.

44. Mobility	I have no problems in walking about	<input type="checkbox"/>
	I have some problems in walking about	<input type="checkbox"/>
	I am confined to bed	<input type="checkbox"/>
45. Self- Care	I have no problems with self- care	
	I have some problems washing or dressing myself	<input type="checkbox"/>
	I am unable to wash or dress myself	<input type="checkbox"/>
46. Usual Activities	I have no problems with performing my usual activities	<input type="checkbox"/>
	I have some problems with performing my usual activities	<input type="checkbox"/>
	I am unable to perform my usual activities	<input type="checkbox"/>

E.g. Work, study, housework, leisure or family activities

47. Pain/Discomfort I have no pain or discomfort ☐
 I have moderate pain or discomfort ☐
 I have extreme pain or discomfort ☐

48. Anxiety/Depression I am not anxious or depressed ☐
 I am moderately anxious or depressed ☐
 I am extremely anxious or depressed ☐

49. In your own opinion, how good or bad is your own health today on a scale of 0-100

(Where 100 is the best imaginable health state and 1 is the worst)

Baby SMART – 4 month questionnaire

Environment

Have you moved house since your last visit?

Yes

☐

No

☐

If Yes: please answer the following:

In what suburb or town do you live?

In what type of area do you live?
 (population < 2000)

☐

Urban

☐

Rural

If you live in a rural area, do you live on a:

Farm

Open countryside

Small town/village

☐
☐
☐

How many people live in your house?

Number of Adults

Number of children

Are you in paid employment at the moment?

Yes

☐
☐

Yes, currently on maternity leave

☐

No

If Yes, how old was your baby when you returned to work?

Age in weeks

Does your baby attend any type of childcare?

Yes

☐

No

☐

If Yes, what type of childcare does your baby attend? (please select all that apply)

Childminder

☐

Hours/week

Creche/Nursery

☐

Minded by a family member (eg. grandparent)

☐

Minded in own home by childminder/aupair

☐

Minded in own home by family member

☐

How old in weeks was your child when he/she first attended child care?

Age in weeks

Have your smoking habits changed since your last visit?

Yes

☐

No

☐

If Yes, please answer the following:

Do you currently smoke?

Yes

☐

No

☐

Yes e-cigarettes only

☐

If Yes, how often do you smoke?

Daily

☐

How many a day

2/3 times a week

☐

Once a week

☐
☐

Less than once a week

Do you allow smoking in your house?

No ☐

Yes, occasionally ☐

Yes, daily ☐

Yes, e-cigarettes only ☐

Is your baby exposed to smoking outside the home (eg. grandparents?)

No ☐

Yes, occasionally ☐

Yes, daily ☐

Yes, e-cigarettes only ☐

How often do you bath your baby?

Once a week ☐

2-3 times a week ☐

3-5 times a week ☐

Daily ☐

Other, please specify

What do you use in the bath?

Please specify product name and brand

How often do you moisturise your baby's skin?

Never ☐

☐

Once a week

☐

2-3 times a week

☐

Daily

☐

Several times a day

☐

Occasionally

What do you use to moisturise your baby's skin?
Please specify product name and brand

Feeding

How are you feeding your baby?

Breast fed

☐

Infant Formula

☐

Both

☐

How many feeds do they get on average in 24 hours?

Breast-milk

☐

Infant formula milk

☐

Solid food

☐

What is the name and brand of the infant formula you are currently giving your baby?

Is your baby fed on a regular schedule eg. every 4 hours?

Yes, always

☐

Yes, try to

☐☐

No, fed on demand

If giving solid foods, how old was he/she when they first had solids?

Age (weeks)

Have you given your baby any vitamins or supplements since your last visit?

Yes

☐

No

☐

If yes, please provide details

Does your baby use a soother/dummy?

Yes, regularly

☐

Yes, occasionally

☐

No

☐

Sleeping

Sleeping Arrangements

Infant cot in separate room

☐

Infant cot in parent's room

☐

In parent's bed

☐

Infant cot in room with sibling

☐

Other, please specify

Sleeping Position

On his / her belly

☐

On his / her side

☐

On his / her back

☐

Sleeping time during the day (between 7am and 7pm)

Hours

Sleeping time during the night (between 7pm and 7am)

Hours

How long does it take to put your baby to sleep in the evening?

Hours Minutes

Wakefulness time between 10pm and 6am

Hours

How does your baby fall asleep?

While feeding

Being rocked

Being held

In bed alone

In bed near parent

When does your baby usually fall asleep at night (24 hour format)?

Time

Do you consider your baby's sleep a problem?

A very serious problem

A small problem

Not a problem

Is it always the same person that puts the baby to bed?

Yes

No

If yes, who is it?

Mother	<input type="checkbox"/>
Father	<input type="checkbox"/>
Other person	<input type="checkbox"/>

Does the baby move in his/her sleep?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

The things that disturb my baby's sleep are: (tick all that apply)

Any sound, even very soft sounds	<input type="checkbox"/>
Radio or TV	<input type="checkbox"/>
People talking	<input type="checkbox"/>
Phone ringing	<input type="checkbox"/>
Other	<input type="checkbox"/>
Nothing disturbs my baby's sleep	<input type="checkbox"/>

When my baby wakes up he/she is usually:

Fussy	<input type="checkbox"/>
Crying	<input type="checkbox"/>
Hungry	<input type="checkbox"/>
Alert but quiet	<input type="checkbox"/>
Alert and active smiling when I approach	<input type="checkbox"/>
Other	<input type="checkbox"/>

My baby can help calm him/herself to sleep by:

Sucking on thumb or fingers	<input type="checkbox"/>
	<input type="checkbox"/>

Holding a favourite blanket or soft toy

Sucking on a soother/dummy

Other

☐
☐

When my baby needs help at night to calm down I:

Pick him/her up

Try talking and gently rubbing his/her back

Play music for him/her

Let him/her cry before I go in

Give him/her a soother/dummy or a bottle

Other

☐
☐
☐
☐
☐
☐

I feel the best way to help my baby sleep through the night is to:

Stick to the same bedtime routine

Feed my baby shortly before putting him/her to bed

Let my baby cry him / herself to sleep

Comforting my baby whenever it's needed

Nothing I do seems to help

Other

☐
☐
☐
☐
☐
☐

Do you know what sleep training is?

Yes

No

☐
☐

Have you tried sleep training?

Yes, The Cry it Out approach

Yes, The No Tears approach

Yes, Fading approach

Yes, Other approaches

No

☐
☐
☐
☐
☐

Will you be trying sleep training?

Yes, The Cry it Out approach

☐

Yes, The No Tears approach

☐

Yes, Fading approach

☐

Yes, Other approaches

☐

No

☐

Did you attend a baby massage course?

Yes

☐

No

☐

If yes, what age was your baby when you started the course (weeks)

Did you use the massage as part of your daily routine?

Yes

☐

No

☐

Sometimes

☐

If yes, what name and brand of product did you use when massaging your baby?

Baby's Health

Has your baby been unwell since or required any medical assistance since your last visit?

Yes

☐

No

☐

If Yes, why?

Weight Loss/ Failure to thrive us

☐

Fever

☐

Reflux

☐

Colic

☐

Skin complaint

Cough

Ear/Eye problem

Vesticoureteric reflux

Pyloric Stenosis

Meningitis

Seizures

Convulsions

Infection

Hernia

Tongue tie

Worried in general

Other

Did you take your baby to the doctor?

Yes

No

If Yes, How many times?

Did your baby need an antibiotic ?

Yes

No

If Yes, how many courses?

Did your baby require admittance to hospital?

Yes

No

If yes, how many times was he/she admitted

Age when last admitted (weeks)

Since your last visit have you given your child pain relief medication?

Yes ☐

No ☐

If Yes, which medication? (please tick all that apply)

Paracetamol eg. Calpol, Paralink ☐

Anti-inflammatories eg. neurofen, brufen ☐

Other, please specify

Since your last visit have you given your child any (that apply)

No ☐

Steroid cream ☐

Teething remedies (non-herbal) ☐

Colic Medication ☐

Reflux medication eg. baby gaviscon ☐

Antifungal creams ☐

Other, please specify

Has your baby received any vaccinations since your last visit?

Yes ☐

No ☐

If yes, please provide details

**Type
in weeks**

Age when received

1. Tuberculosis (BCG)

2. 2 month, 6 in 1 (polio, diphtheria, whooping cough, tetanus, HepB, H influenza B plus Men C)

3. 4 month, 6 in 1 (polio, diphtheria, whooping cough, tetanus, HepB, H influenza B plus Men C)

4. Other, please specify

Mother's health

Were you prescribed any medication since your child was born?

Yes

☐

No

☐

If YES, what were you prescribed?

If YES, how long did you have to take it for?

Days

Weeks

For Mothers only - Mother's Quality of Life

We would like for you to answer a few questions about your current health state.

Please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

☐
☐
☐

Self- Care

I have no problems with self- care

I have some problems washing or dressing myself

I am unable to wash or dress myself

☐
☐
☐

Usual Activities

I have no problems with performing my usual activities

☐
☐

I have some problems with performing my usual activities
 I am unable to perform my usual activities
 E.g. Work, study, housework, leisure or family activities ☐

Pain/Discomfort

I have no pain or discomfort	<input type="checkbox"/>
I have moderate pain or discomfort	<input type="checkbox"/>
I have extreme pain or discomfort	<input type="checkbox"/>

Anxiety/Depression

I am not anxious or depressed	<input type="checkbox"/>
I am moderately anxious or depressed	<input type="checkbox"/>
I am extremely anxious or depressed	<input type="checkbox"/>

In your own opinion, how good or bad is your own health today on a scale of 0-100
 (Where 100 is the best imaginable health state and 1 is the worst)

For Mothers only - Attachment Questionnaire

1. When I am caring for the baby, I get the feeling of annoyance or irritation

- Very frequently ☐
- Frequently ☐
- Occasionally ☐
- Very rarely ☐
- Rarely ☐

2. When I am caring for the baby I get the feeling that the child is deliberately being difficult or trying to upset me

- Very frequently ☐
- Frequently ☐
- Occasionally ☐
- Very rarely ☐
- Rarely ☐

3. Over the last two weeks I would describe my feelings for the baby as:

- Dislike ☐
- No strong feelings towards the baby ☐
- Slight affection ☐
- Moderate affection ☐
- Intense affection ☐

4. Regarding my overall level of interaction with the baby, I:
- Feel very guilty that I am not more involved ☐
 - Feel moderately guilty that I am not more involved ☐
 - Feel slightly guilty that I am not more involved ☐
 - I don't have any guilty feelings regarding this ☐
5. When I interact with the baby I feel:
- Very incompetent and lacking in confidence ☐
 - Moderately incompetent and lacking in confidence ☐
 - Moderately confident and competent ☐
 - Very confident and competent ☐
6. When I am with the baby I feel tense and anxious:
- Very frequently ☐
 - Frequently ☐
 - Occasionally almost never ☐
7. When I am with the baby and other people are present I feel proud of the baby:
- Very frequently ☐
 - Frequently ☐
 - Occasionally ☐
 - Almost never ☐
8. I try to involve myself in as much as possible PLAYING with the baby:
- This is true ☐
 - This is untrue ☐
9. When I have to leave the baby:
- I usually feel rather sad (or it's difficult to leave) ☐
 - I often feel rather sad (or it's rather difficult to leave) ☐
 - I have mixed feelings of both sadness and relief ☐
 - I often feel rather relieved (and it is easy to leave) ☐
 - I usually feel rather relieved (and it is easy to leave) ☐
10. When I am with the baby:
- I always get a lot of enjoyment /satisfaction ☐
 - ☐

- I frequently get a lot of enjoyment /satisfaction
- I occasionally get a lot of enjoyment/satisfaction
- I rarely get a lot of enjoyment/satisfaction

☐
☐

11. When I am not with the baby, I find myself thinking about the baby:

- Almost all the time
- Very frequently
- Frequently
- Occasionally
- Never

☐
☐
☐
☐
☐

12. When I am with the baby:

- I usually try to prolong the time I spend with him/her
- I usually try to shorten the time I spend with him/her

☐
☐

13. When I have been away from the baby for a while and I am about to be with him/her again, I usually feel:

- Intense pleasure at the idea
- Moderate pleasure at the idea
- Mild pleasure at the idea
- No feelings at all about the idea
- Negative feelings about the idea

☐
☐
☐
☐
☐

14. I now think of the baby as:

- Very much my own baby
- A bit like my own baby
- Not yet really my own baby

☐
☐
☐

15. Regarding the things that I/we have had to give up because of this baby:

- I find that I resent it quite a lot
- I find that I resent it a moderate amount
- I find that I resent it a bit
- I don't resent it at all

☐
☐
☐
☐

16. Over the past 3 months, I have felt that I do not have enough time for myself:

- Almost all the time ☐
- Frequently ☐
- A few times ☐
- Not at all ☐

17. Taking care of this baby is a heavy burden of responsibility. I believe this is:

- Very much so ☐
- Somewhat so ☐
- Slightly so ☐
- Not at all ☐

18. I trust my own judgement in deciding what my baby needs:

- Very much so ☐
- Somewhat so ☐
- Slightly so ☐
- Not at all ☐

19. Usually when I am with the baby:

- I am very impatient ☐
- I am a bit impatient ☐
- I am moderately patient ☐
- I am extremely patient ☐

For Mothers only – Edinburgh PND score

Instructions: Please tick one option for each question that is closest to how you have felt for the PAST SEVEN DAYS

1. I have been able to laugh and see the funny side of things

- As much as I always could ☐
- Not quite as much now ☐
- Definitely not so much now ☐
- Not at all ☐

2. I have looked forward with enjoyment to things

☐

- As much as I ever did
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

3. I have blamed myself unnecessarily when things went wrong

- Yes, most of the time ☐
- Yes, some of the time ☐
- Not very often ☐
- No, never ☐

4. I have been anxious or worried for no good reason

- No, not at all ☐
- Hardly ever ☐
- Yes, sometimes ☐
- Yes, very often ☐

5. I have felt scared or panicky for no very good reason

- Yes, quite a lot ☐
- Yes, sometimes ☐
- No, not much ☐
- No, not at all ☐

6. Things have been getting on top of me

- Yes, most of the time I haven't been able to cope at all ☐
- Yes, sometimes I haven't been coping as well as usual ☐
- No, most of the time I have coped quite well ☐
- No, I have been coping as well as ever ☐

7. I have been so unhappy that I have had difficulty sleeping

- Yes, most of the time ☐
- Yes, sometimes ☐
- Not very often ☐
- No, not at all ☐

8. I have felt sad or miserable:
- Yes, most of the time ☐
 - Yes, quite often ☐
 - Only occasionally ☐
 - No, never ☐

9. I have been so unhappy that I have been crying
- Yes, most of the time ☐
 - Yes, quite often ☐
 - Only occasionally ☐
 - No, never ☐

10. The thought of harming myself has occurred to me
- Yes, quite often ☐
 - Sometimes ☐
 - Hardly ever ☐
 - Never ☐
- NB if you have any thoughts of harming yourself, please tell us today

Baby SMART – 18 month questionnaire

Environment

Have you moved house since your last visit?

- Yes ☐
- No ☐

If Yes: please answer the following:

In what suburb or town do you live?

In what type of area do you live? Urban ☐ Rural ☐ (population<2000)

If you live in a rural area, do you live on a:

Farm ☐

Open countryside ☐

Small town/village ☐

How many people live in your house?

Number of Adults

Number of children

Do you work in paid employment at the moment?

Yes

☐

No

☐

If Yes, how old was your baby when you returned to work?

Age in months

If your child **attends childcare** please fill out the table below, recording all forms of childcare. If your child **does not attend** any childcare, please tick does not attend.

Type of childcare	How many hours spent per week in childcare	How many other children minded
Child minder		
Nursery/Creche		
Minded by family member (e.g. grandparent)		
Minded in own home by child minder or au pair		
Minded in own home by family member		
Does not attend (minded by mum and dad)		

Have your smoking habits changed since your last visit?

Yes

☐

No

☐

If Yes, please answer the following:

Do you currently smoke?

Yes

☐

No

☐

Yes e-cigarettes only

☐

If Yes, how often do you smoke?

Daily

How many a day

2/3 times a week

Once a week

Less than once a week

Do you allow smoking in your house?

No

Yes, occasionally

Yes, daily

Yes, e-cigarettes only

Is your baby exposed to smoking outside the home (eg. grandparents?)

No

Yes, occasionally

Yes, daily

Yes, e-cigarettes only

How often do you bath your baby?

Once a week

2-3 times a week

3-5 times a week

Daily

Other, please specify

What do you use in the bath?

Please specify product name and brand

How often do you moisturise your baby's skin?

Never

☐

Once a week

☐

2-3 times a week

☐

Daily

☐

Several times a day

☐

Occasionally

What do you use to moisturise your baby's skin?

Please specify product name and brand

Feeding

Does your child still take a bottle?

Yes

☐

No

☐

If Yes, how many bottles a day do they take of the following

• Infant formula

☐

• Growing up milk

☐

• Cow's milk

☐

• Other

☐

○ If other please specify

Does your baby use a soother/dummy?

Yes, regularly

☐

Yes, occasionally

☐

No

☐

Sleeping

Sleeping Arrangements

Infant cot in separate room

☐

Infant cot in parent's room	<input type="checkbox"/>
In parent's bed	<input type="checkbox"/>
Infant cot in room with sibling	<input type="checkbox"/>
Other, please specify	<input type="text"/>

Sleeping Position

On his / her belly	<input type="checkbox"/>
On his / her side	<input type="checkbox"/>
On his / her back	<input type="checkbox"/>

Sleeping time during the day (between 7am and 7pm)

Hours

Sleeping time during the night (between 7pm and 7am)

Hours

How long does it take to put your baby to sleep in the evening?

Hours Minutes

Wakefulness time between 10pm and 6am

Hours

How does your baby fall asleep?

While feeding	<input type="checkbox"/>
Being rocked	<input type="checkbox"/>
Being held	<input type="checkbox"/>
In bed alone	<input type="checkbox"/>
In bed near parent	<input type="checkbox"/>

When does your baby usually fall asleep at night (24 hour format)?

Time

Do you consider your baby's sleep a problem?

A very serious problem ☐

A small problem ☐

Not a problem ☐

Is it always the same person that puts the baby to bed?

Yes ☐

No ☐

If yes, who is it?

Mother ☐

Father ☐

Other person ☐

Does the baby move in his/her sleep?

Yes ☐

No ☐

The things that disturb my baby's sleep are: (tick all that apply)

Any sound, even very soft sounds ☐

Radio or TV ☐

People talking ☐

Phone ringing ☐

Other ☐

Nothing disturbs my baby's sleep ☐

When my baby wakes up he/she is usually:

Fussy ☐

Crying	<input type="checkbox"/>
Hungry	<input type="checkbox"/>
Alert but quiet	<input type="checkbox"/>
Alert and active smiling when I approach	<input type="checkbox"/>
Other	<input type="checkbox"/>

My baby can help calm him/herself to sleep by:

Sucking on thumb or fingers	<input type="checkbox"/>
Holding a favourite blanket or soft toy	<input type="checkbox"/>
Sucking on a soother/dummy	<input type="checkbox"/>
Other	<input type="checkbox"/>

When my baby needs help at night to calm down I:

Pick him/her up	<input type="checkbox"/>
Try talking and gently rubbing his/her back	<input type="checkbox"/>
Play music for him/her	<input type="checkbox"/>
Let him/her cry before I go in	<input type="checkbox"/>
Give him/her a soother/dummy or a bottle	<input type="checkbox"/>
Other	<input type="checkbox"/>

I feel the best way to help my baby sleep through the night is to:

Stick to the same bedtime routine	<input type="checkbox"/>
Feed my baby shortly before putting him/her to bed	<input type="checkbox"/>
Let my baby cry him / herself to sleep	<input type="checkbox"/>
Comforting my baby whenever it's needed	<input type="checkbox"/>
Nothing I do seems to help	<input type="checkbox"/>

Other

Do you know what sleep training is?

Yes

No

Have you tried sleep training?

Yes, The Cry it Out approach

Yes, The No Tears approach

Yes, Fading approach

Yes, Other approaches

No

Will you be trying sleep training?

Yes, The Cry it Out approach

Yes, The No Tears approach

Yes, Fading approach

Yes, Other approaches

No

Did you attend a baby massage course?

Yes

No

If yes, what age was your baby when you started the course (weeks)

Did you use the massage as part of your daily routine?

Yes

No

Sometimes

If yes, what name and brand of product did you use when massaging your baby?

Screen –time

Does your child use a touch-screen device?

Never

☐

Rarely (<1/week)

☐

Occasionally (1-2 / week)

☐

Regularly (3-5 / week)

☐

Daily

☐

If your child uses a touch-screen device Regularly or Daily, how long on average do they spend on the device?

5-10 minutes

☐

10-20 minutes

☐

20-40 minutes

☐

40-60 minutes

☐

60-90 minutes

☐

90-120 minutes

☐

>120 minutes

☐

What are your child's main activities when using the touch-screen device (Please tick all that apply)

Interacting with fun toddler games/puzzles

☐

Interacting with educational game/puzzles

☐

Watching TV shows/videos/ cartoons

☐

Reading E books

☐

Swiping photographs

☐

Baby's Health

Has your baby been unwell since or required any medical assistance since your last visit?

Yes ☐

No ☐

If Yes, why?

Weight Loss/ Failure to thrive us ☐

Fever ☐

Reflux ☐

Colic ☐

Skin complaint ☐

Cough ☐

Ear/Eye problem ☐

Vesticoureteric reflux ☐

Pyloric Stenosis ☐

Meningitis ☐

Seizures ☐

Convulsions ☐

Infection ☐

Hernia ☐

Tongue tie ☐

Worried in general ☐

Other

Did your baby require admittance to hospital?

Yes ☐

No ☐

If yes, how many times was he/she admitted

Age when last admitted (weeks)

Has your baby received any vaccinations since your last visit?

Yes

☐

No

☐

If yes, please provide details

**Type
in weeks**

Age when received

6 month, 6 in 1 (polio, diphtheria, whooping cough, tetanus, Hep B, H influenza B plus Men C)

plus PCV & Men C

12 month, MMR & Men B

13 month, Men C + Hib, plus PCV

Other, please specify

Mother's health

Were you prescribed any medication since your child was born?

Yes

☐

No

☐

If YES, what were you prescribed?

If YES, how long did you have to take it for?

Days

Weeks

Mother's Quality of Life

We would like for you to answer a few questions about your current health state.

Please indicate which statements best describe your own health state today.

Mobility	I have no problems in walking about	<input type="checkbox"/>
	I have some problems in walking about	<input type="checkbox"/>
	I am confined to bed	<input type="checkbox"/>
Self- Care	I have no problems with self- care	<input type="checkbox"/>
	I have some problems washing or dressing myself	<input type="checkbox"/>
	I am unable to wash or dress myself	<input type="checkbox"/>
Usual Activities E.g. Work, study, housework, leisure or family activities	I have no problems with performing my usual activities	<input type="checkbox"/>
	I have some problems with performing my usual activities	<input type="checkbox"/>
	I am unable to perform my usual activities	<input type="checkbox"/>
Pain/Discomfort	I have no pain or discomfort	<input type="checkbox"/>
	I have moderate pain or discomfort	<input type="checkbox"/>
	I have extreme pain or discomfort	<input type="checkbox"/>
Anxiety/Depression	I am not anxious or depressed	<input type="checkbox"/>
	I am moderately anxious or depressed	<input type="checkbox"/>
	I am extremely anxious or depressed	<input type="checkbox"/>

In your own opinion, how good or bad is your own health today on a scale of 0-100
 (Where 100 is the best imaginable)