ISRCTN66710572 https://doi.org/10.1186/ISRCTN66710572

Little in Norway (LiN) study

Submission date 20/03/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/05/2018	**Overall study status** Completed	
Last Edited 23/11/2020	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The aim of this study is to investigate risk factors before and after birth that affect early childhood emotional regulation and development from pregnancy to child age 3 years.

Who can participate?
Pregnant women receiving routine prenatal care at well-baby clinics at nine sites across Norway

What does the study involve?
Data is collected at five points in pregnancy, birth, and five follow-up points up to age 3. Questionnaires are completed by both parents, hair, urine, blood and saliva samples are taken from the mother and child, there are direct observations and testing of the children, and videotaping of parent–child interaction. Questionnaires about infant behaviour and development and parental mental health and diet are filled out when the families attend the site, and web-based forms are completed from home.

What are the possible benefits and risks of participating?
A possible benefit for the parents and their children is that their development is followed closely and with the opportunity to refer them to the relevant services if and when there is a need for such referrals. Attending all the follow-ups in the study may be time-consuming for the parents. Concerning blood samples only experienced nurses are employed to heighten security. In addition, all participants are told that the blood sampling is voluntary and that they could take part in the study without going through the blood sampling.

Where is the study run from?
University of Oslo (Norway)

When is the study starting and how long is it expected to run for?
January 2010 to December 2016

Who is funding the study?
Research Council of Norway

Who is the main contact?
Dr Vibeke Moe

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Norwegian Research Council Grant #196156

Study information

Scientific Title
A longitudinal population study of infant vulnerability and plasticity from pregnancy to age 18 months

Acronym
LiN

Study objectives
The study aims to acquire new knowledge of critical factors affecting early childhood emotional regulation and development, as well as to gain better understanding of mechanisms and differential biological plasticity related to infant mental health outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norwegian Regional Committees for Medical and Health Research Ethics, 24/05/2011, ref: 2011/560

Study design

Prospective longitudinal multisite community-based study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Child development

Interventions
The overarching objective of the present project is to investigate how very young Norwegian children fare in the sensory-motor and social-emotional domains, and how susceptible children may be adversely affected by stressors and potentially benefit from intervention: (1) Who are the most susceptible to delayed sensory-motor development and emotional adversity? And (2) who will potentially benefit from intervention? The study aims to assess a wide array of environmental stress, including both biomedically and environmentally mediated stressors as well as parent-reported stress factors. Susceptibility and resilience will be studied by examining child development over time related to externalizing internalizing behaviors (e.g. anxiety) and emotion dysregulation. Outcome measures will cover a wide range of possible sequelae.

Pre- and postnatal risk factors influencing developmental plasticity are investigated from pregnancy to age 18 months. A web-based questionnaire is also distributed at child age 3 years. Data collection phases comprised five points in pregnancy, birth, and five follow-up points up to age 3. The main categories of data include questionnaires completed repeatedly by both parents, biological samples of mother and child, direct observations and testing of the children, and videotaping of parent–child interaction. Questionnaires related to infant behavior and development as well as to parental mental health and dietary intake were filled out when the families attended the site, and as web-based forms from home. Biological samples include saliva, hair, urine and blood samples.

Intervention Type
Other

Primary outcome measure
Child outcome and possible diagnostic information based on repeated observations of parent–child interaction, developmental testing, and parent and preschool teacher report measures:

Data collection in the Little in Norway study has comprised five points in pregnancy (weeks 16, 20, 26, 32, 36), time of birth, 6 weeks postpartum, 6,12 and 18 months and 3 years. Data have

been collected through self-report questionnaires filled out at home, at well baby clinics or completed by research assistants based on parent interviews, and by testing and observation of the child, telephone interviews and video sessions. All completed questionnaires, test protocols and video recordings were streamed to a central facility where they were registered, verified and kept on a secure server. The questionnaires that were completed at home used a web-based survey motor provided by one of the study's data processors.

A comprehensive questionnaire package was given to the participating mothers and fathers at the first meeting in pregnancy, which could take place from pregnancy week 8 to 34, depending on the specific time of enrolment. The questionnaire package included queries concerning sociodemographic background, smoking, use of alcohol, drugs and medication in pregnancy, as well as the following measures:
1. The Life Stress Scale (a subscale of the Parenting Stress Index, PSI), measuring parental stress factors over the previous 12 months
2. The Pregnancy Related Anxiety Questionnaire (PRAQ R), designed to assess anxiety related to pregnancy and birth
3. The Edinburgh Postnatal Depression Scale (EPDS), a self-report measure identifying women at risk for perinatal depression
4. The Adverse Childhood Experience Scale (ACE), assessing possible parental adverse childhood experiences prior to age 18 years
For all but the latest enrolled families, most of the procedures applied at the first meeting were repeated at follow-ups later in pregnancy. When a project infant was born, the research assistant at the site collected information from hospital birth records.

At 6 weeks after birth the research assistants met with the parents and their baby to observe the infant and to obtain information about the child's diurnal rhythm. Questionnaires were given to the parents and biological samples from the mother and the child were collected:
EPDS (6 weeks, 6, 12, 18 months) and PSI (long version) answered by the parents also after birth (6, 12, 18 months)
1. The child's developmental skills were assessed by testing the child's cognitive, language, and fine- and gross motor development using the screening (6 and 12 months) or the full version (18 months) of the Bayley Scales of Infant and Toddler Development, third edition (Bayley-III)
2. The infants' possible social withdrawal reactions were observed in a standardized way (using the Alarm Distress Baby Scale) based on child behaviour when completing the Bayley
3. Infant social emotional functioning assessed in a videotaped interaction session, first with one of their parents present and then with the other, and subsequently coded by means of the Relational Health Screen.
4. Perceived temperament of the participating infants assessed with a questionnaire at 6 and 12 months
5. Child social emotional functioning assessed in a sub-sample by a standardised telephone interview, based on Infant–Toddler Social–Emotional Assessment (ITSEA), with the main caregiver at 12 months. At 18 months, ITSEA was completed by all parents at the site, and also by the child's preschool teacher if the child attended a day-care centre. At 3 years a web-based Version of the questionnaire ITSEA was completed from home

Secondary outcome measures

1. Dietary intake was assessed using a web-based, semi-quantitative food frequency questionnaire, the Seafood-FFQ. The questionnaire is designed to capture the habitual intake of seafood and the use of dietary supplements. To enable aggregation and quantity estimation of individual seafood consumption, ordinal data from the Seafood-FFQ is converted to numerical data using the seafood-index system. At 3 years a web-based FFQ of mothers and children's food habits was applied.

2. Nutritional status and suboptimal nutritional status of micronutrients like DHA, vitamin D and iodine, assessed using hair, urine, and blood samples collected repeatedly through follow-up (at inclusion in pregnancy, 6 weeks, 6 months, 12 months and 18 months)
3. Cortisol level measured using hair samples from mothers 6 weeks and 12 months postpartum
4. DNA methylation assayed using saliva samples collected by the research assistants at 6 weeks and 12 months (from the child and the mother)

Overall study start date
01/01/2010

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Pregnant women were enrolled from September 2011 to October 2012
2. All pregnant women receiving routine prenatal care at well-baby clinics at nine geographically diverse sites across Norway were invited by midwives to participate
3. Most pregnant women were at week 11-26 into gestation when they completed the first questionnaire; however, some women were asked as late as week 31-34

Participant type(s)
All

Age group
Mixed

Sex
Both

Target number of participants
1036 pregnant women were included

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2011

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Norway

Study participating centre
University of Oslo
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Sponsor information

Organisation
University of Oslo

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Sponsor type
University/education

ROR
https://ror.org/01xtthb56

Funder(s)

Funder type
Government

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Publication and dissemination plan
The trialists are currently working on a cohort profile paper where the study protocol will be available. They plan to submit the article to a high-impact peer reviewed journal in June 2018. Publications are planned in high-impact peer reviewed journals in the near future.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The type of data stored are SPSS files, as well as video recordings of parent-infant interactions, in addition to biological samples. At inclusion each participant (mother and father) was informed about the purpose of the study. Confidentiality was assured, and it was emphasized that participation was voluntary and could be withdrawn at any time. The study protocol and the assessment procedures were reviewed and approved by the Norwegian Regional Committees for Medical and Health Research Ethics, reference number 2011/560. All procedures were in accordance with these ethical standards and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Parts of the data are highly sensitive and may be identifiable, there is therefore presently both ethical and legal restrictions concerning accessibility. The ethics approval state that data shall be stored until 2030.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/12/2019	23/11/2020	Yes	No