Plan Overview

A Data Management Plan created using DMPonline

Title: Effects of early nutrition on brain development and cognitive / behavioural problems in children

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Funder: Swedish Research Council

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Project abstract:

Cognitive and behavioural problems are common in children and early nutrition is a causal factor of public health importance. Deficiencies of some key micronutrients (iron, iodine, selenium and vitamin D) have recently been shown to be a remaining or even increasing public health problem among pregnant women and young children in Sweden. Another challenge is the poorer cognitive development of formula-fed infants, as compared to breastfed infants, which may be related to bioactive components of human milk. Preterm infants in Sweden are at high risk of malnutrition, which may impair their neurodevelopment. Our overall hypothesis is that improved early nutrition may be an effective strategy to reduce cognitive and behavioural problems in Swedish children. In this project, we propose to investigate the effects of early nutrition on brain development at different developmental stages using a wide array of methods, including four randomized, clinical intervention trials, several population-based cohort studies as well as mechanistic studies, in both males and females. The specific aims are: 1. To determine in a series of randomized, controlled trials (RCT:s) whether early nutrition interventions aimed at specific risk groups improve neurodevelopmental test scores at pre-school and school age, without adverse effects: A. Iron supplementation of healthy, breast-fed infants B. Iodine and selenium supplementation of pregnant women C. Milk fat globule membrane (MFGM) supplementation of healthy, formula-fed infants D. A human milk based fortifier (HMF) for extremely preterm infants 2. To investigate in a large, new population-based birth cohort how early intakes and biomarkers of key micronutrients and bioactive human milk components are associated with neurodevelopmental scores later in childhood. This includes some novel biomarkers, e.g. hepcidin, erythroferrone, endocannabinoids, N-acylethanolamine lipids and gangliosides, as well as novel neurodevelopmental test methods. 3. To determine in population-based cohorts of preterm infants how early nutritional factors are associated with cognitive and/or behavioural test scores later during childhood and structural changes, as assessed by brain magnetic resonance imaging (MRI).

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Effects of early nutrition on brain development and cognitive / behavioural problems in children

General Information

Project Title

Effects of early nutrition on brain development and cognitive / behavioural problems in children

Project Leader

Professor Magnus Domellöf, Dept of Clinical Sciences, Umeå University

Registration number at the Swedish Research Council

2019-01005

Version

2

Date

20 Nov 2023

Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

Data is collected from several ongoing clinical trials (SIDBI, SWIDDICH, TUMME, N-FORTE) and cohort studies (NorthPop, EXPRESS, EXPRESS 2, LIGHT, PUMPA).

The data collections consist of

1. Health data collected using questionnaires, hospital records and registers.
2. Biological material (blood, urine, feces, saliva, breast milk) collected at different time points. These samples will be analysed and the results of the analyses will be added to the database.

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

Data formats include health data and biological material.

The total number of study participants in this VR project will be more than 30 000 individuals. The highest number of individuals are from the NorthPop cohort.

The number of data points per indivudual is variable between the substudies, but may be as many as 100 000 or more.

Data formats include proprietary systems (Confirmit), Excel format etc.

Up to 50 GB data volume

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

All data is coded by individual patient without unnecessary identifiable information like names, personal numbers or addresses and all data is gathered into a database, ensuring good quality control and traceability of all data.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

Repeated measurements, i.e. longitudinal measurements, are performed in most substudies. Validation of data input is performed continuously in subsamples.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

The main database is hosted by Registercentrum Norr at Region Västerbotten, with support from Umeå University ITS. The database is kept behind a firewall and password protected. Additional databases are stored in a secure storage area ("Trygg Filyta") hosted by Umeå University, with a backup on a non-network-connected hard disk kept in a locked room at the Department of Clinical Sciences. A full time data manager is responsible for secure data handling.

Description in Swedish of 'Trygg Filyta':
’Trygg Filyta’ utgör en säker och lokal lagringsplats/filyta för digitala dokument.
Servermiljö
Underliggande servermiljö ligger i Umeå universitets lokala hallar och innanför ett skalskydd, larm och inpasseringskontroll, dit bara de av ITS utsedd personal har access. Servers är logiskt separerade och innanför perimeterskydd (Brandvägg).
Användare
De användare som ska ha access till Trygg Filyta måste ha Swamid AL2 samt multifaktorautentisering(MFA) aktiverat.
Inloggning
Inloggning sker via webgränssnitt (TLS) och MFA, dvs. användarkonto + lösenord + engångskod från en annan enhet. All inloggning och filöverföring är krypterad via TLS.
Access
Accesstilldelning styrs helt av informationsansvarig för respektive filyta. Behörigheterna på dokument kan vara fullständiga, redigera eller läsa. För att fler ska få access till ytan måste informationsansvarig beställa access för dessa användare som också de måste uppfylla kravet på Swamid AL2
Dokumenthanteringssystem
Tjänsten som används för att underlätta dokumenthanteringen är SharePoint 2019, som är ständigt säkerhetsuppdaterad. SharePoint 2019 är konfigurerad enligt rekommendationer för hög säkerhet ex. begränsat möjlighet att dela dokument. All åtkomst loggas så att det finns spårbarhet vem som har laddat upp, sökt, öppnat eller laddat ned en fil.
Backup
Backup tas dagligen. Vid återläsning av backup krävs en dekryptering för åtkomst till data.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

The main database is kept behind a firewall and password protected. Additional databases are stored in a secure storage area ("Trygg Filyta") hosted by Umeå University, with a backup on a non-network-connected hard drive, kept in a locked room at the Department of Clinical Sciences. A full time data manager is responsible for secure data handling.
Personal data (name, personnummer, address) is kept separate from the main database, which uses only study ID.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

All data collection and data handling is approved by the Ethical committee and by informed consent from the study participants. All data handling is done in accordance with GDPR.

How is correct data handling according to ethical aspects safeguarded?

All data collection and data handling is approved by the Ethical committee and by informed consent from the study participants. All data is removed upon request from study participants.

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

Metadata will be published at the Swedish National Dataservice (SND) repository within the project period.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

Long-term storage is planned for all data. Our data manager is responsible for data storage, in collaboration with Registercentrum Norr, Region Västerbotten and Umeå University ITS.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

Long term storage of data will be done in generic formats for easy access also in the future.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

Unique and persistent identifiers of individual data points are only available to study coordinators and the data manager within our closed database.
DOIs for datasets will be provided by SND.

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

The project data manager is Richard Lundberg.
Yulia Blomstedt is responsible for the databases within Registercentrum Norr.
Dan Harnesk is responsible for information security at Umeå University.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

A full time data manager employed by the PI is required. Access to secure servers at Region Västerbotten and Umeå University is

required.
Resources are needed to publish metadata according to the FAIR principles.