

Improving dietary habits and feeding practices in the critical early phases of life using e-learning resources

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
14/06/2022	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
19/06/2022	Ongoing	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
20/01/2025	Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Poor diet quality is a leading cause of the global epidemic of non-communicable diseases (NCD), resulting in large disease-related negative impacts well beyond the health sector. The understanding of how life-long health is rooted in conditions early in life has developed enormously over the past 40 years, and it has become clear that early-life nutrition strongly influences health throughout life. Still, there is a critical lack of public health action and response to these insights.

Who can participate?

Pregnant women, parents of children aged 0 to 2 years, kindergarten personnel, health care centre personnel, municipality staff, and parents from marginalized groups.

What does the study involve?

In Nutrition Now, we will address NCD prevention through investments in dietary care in the first 1000 days of life. The project acts on the existing evidence-to-practice gap; that successful interventions are not being implemented at scale for the benefit of population health and community resilience. We have previously developed several e-learning interventions targeting nutrition, evaluated in controlled settings, showing promising results. They address diet during pregnancy, infancy, and toddlerhood, and include kindergarten educational tools. Now, we will scale up and implement the interventions in a community setting tailored to context and users' needs, especially those from less advantaged groups. The effectiveness will be assessed in one municipality versus control before moving on to a fully scaled-up program at the county level.

What are the possible benefits and risks of participating?

We will advance the field by investigating the potential cumulative health effects of a life-course intervention approach and implementing multiple, low-cost, equitable, evidence-based e-learning resources at scale. The project harnesses an untapped potential for improving nutrition in early life through improved dietary guidance in primary health care and better feeding practices in kindergartens. There are no risks taking part in this study for the individual included in the intervention, for the underserved groups being interviewed, they might bring up issues

themselves that may relate to feelings of not managing child feeding in a good way. Only professional interviewers will conduct these interviews.

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

When is the study starting and how long is it expected to run for?
December 2020 to December 2026

Who is funding the study?
The Norwegian Research Council (Norway)

Main contact
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
320521

Study information

Scientific Title

Scaling up evidence-based early-life nutrition interventions for community resilience and life-course health (Nutrition Now)

Study objectives

We hypothesise that successful adaptation and implementation of the e-learning resources at a large scale in a real-world setting will improve dietary habits and feeding practices in the critical early phases of life (first 1000 days), which are valid proxy endpoints for future health outcomes and cost-effectiveness over the life course

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 09/12/2021, Regional Ethics Committee (Sør-Øst A, Gullhaugveien 1-3, 0484 Oslo, Norway; +47 22 84 55 11; rek-sorost@medisin.uio.no), ref: REC 322480.
2. Approved 24/01/2022, Faculty Ethical Committee (Universitetet i Agder, PO box 422, 4604 Kristiansand, Norway; +47 38141866; eli.andas@uia.no), ref: FEC 24/01/2022.
3. Approved 13/01/2022, Norwegian Data Protection Service (Norwegian Centre for Research Data, Harald Hårfagres gate 29, N-5007 Bergen, Norway; +47 55 58 21 17; nsd@nsd.no), ref: NSD 847590.

Study design

Current study design as of 28/09/2022:

Single-centre non-randomized interventional hybrid type I study

Previous study design:

Single-centre non-randomized interventional hybrid type II study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Promotion of healthy dietary habits in early life

Interventions

We have previously developed several interventions targeting pregnancy diet, parental feeding practices in relation to child diet, and early childhood education and care (ECEC) diet. These interventions have all shown to be promising in efficacy trials. In Nutrition Now these interventions will be combined and implemented at the community and county levels. The interventions are digital, largely video-based, and grounded in social cognitive theory, addressing the interaction between person, environment, and behaviour. In Nutrition Now, we will tailor our e-learning interventions to pregnant women and parents recruited through primary health care and tailor them to ECEC staff's routines and schedules.

Participants receiving the intervention will have access from pregnancy to a child age of 2 years. They will receive monthly and biweekly (dependent on child age) messages, and they can also access all parts of the digital e-learning resources at all times.

The part targeting kindergartens is an intervention of 5 months that can be prolonged and adapted to the different kindergartens' settings.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 28/09/2022:

Aspects of child diet quality, represented by intake of vegetables, fruits and berries, legumes /pulses and sugar sweetened beverages. Measured by questionnaires at baseline and at different ages depending on the age of the child when included in the study (at 6 weeks, 6 months, 12 months, 18 months, 24 months)

Previous primary outcome measure:

Diet and diet-related behaviors in early life, measured by questionnaires at baseline and at different ages depending on the age of the child when included in the study (at 6 weeks, 6 months, 12 months, 18 months, 24 months)

Key secondary outcome(s)

1. Parental and kindergarten staff feeding practices measured by questionnaires at baseline and 6 months (kindergarten), and at child ages 6 weeks, 6 months, 12 months, 18 months, 24 months
2. Maternal diet during pregnancy, measured by questionnaire at baseline
3. Maternal quality-of-life (pregnancy and later), measured with the Satisfaction with Life Scale at baseline
4. Breastfeeding rates, measured by questionnaire at baseline, ages 6 and 12 months
5. Anthropometric measures (parental and child), measured by self-reporting at baseline and at 6 weeks, 6 months, 12 months, and 18 months
6. Health-related quality of life (infant), measured with the Infant Quality of Life Scale at 6 weeks, 6 months, 12 months, and 18 months
7. Implementation costs, estimated through the study period
8. Child development, measured by Ages and Stages questionnaire at 18 months
9. Cost-effectiveness, evaluated using points 5, 6, 7, and 8 above at 18 months
(added 28/09/2022)
10. Child eating enjoyment measured by Child Eating Enjoyment Scale (Data will be collected from ECEC staff at baseline and post-intervention (7 months after intervention start) and data will be collected from parents in at child age 12 months, 18 and 24 months)
11. Pregnancy complications measured by questionnaire (parental questionnaires at child age 6 weeks)
12. ECEC fruit and vegetable availability measured by receipts of fruit and vegetables bought (pre intervention and continuously until the end of data collection)
13. Municipal spend on activities related to early childhood nutrition and feeding practices (budget data from 2021-2024)

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Pregnant women
2. Parents of children aged 0 to 2 years old
3. Kindergarten staff
4. Municipality personnel
5. Persons from marginalized groups

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/10/2022

Date of final enrolment

01/07/2023

Locations

Countries of recruitment

Norway

Study participating centre

University of Agder

PO box 422

Kristiansand

Norway

4604

Sponsor information

Organisation

University of Agder

ROR

<https://ror.org/03x297z98>

Funder(s)

Funder type

Research council

Funder Name

Norges Forskningsråd

Alternative Name(s)

Forskningsrådet, Norwegian Research Council, Research Council of Norway, The Research Council of Norway

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Norway

Results and Publications

Individual participant data (IPD) sharing plan

We plan to share anonymized data in the UiA deposit Dataverse, <https://dataverse.no/dataverse/uia>. This will be done no later than the acceptance for publication of the main findings from the final dataset (01/06/2025). We will retain our data for five years after data collection has stopped (meaning that data from our baseline will be available no later than 2027 or on publication of main findings). Standard meta-information about the data will be uploaded.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/01/2023	30/01/2023	Yes	No
Protocol article	national scale-up of Nutrition Now	09/01/2024	24/01/2024	Yes	No
Other publications	Qualitative results	05/06/2024	05/06/2024	Yes	No
Other publications	Staff perspectives	20/09/2024	24/09/2024	Yes	No
Other publications	Staff's perceptions and needs	30/10/2024	01/11/2024	Yes	No
Other publications	Implementation strategies: lessons learned	13/01/2025	20/01/2025	Yes	No

<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Study website</u>	Study website	11/11/2025	11/11/2025	No	Yes