

Mammas mat

Protocol for the study on pregnant women

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Nordic Iodine Meeting 16-17 September 2015



Iodine status during pregnancy and its effect on infant development; a randomized intervention trial with cod

Short title: Mammass mat (NO), Mommy's food (EN)



Partners



- Scientific
 - NIFES: Maria Wik Markhus, Marian Kjellevold Malde, Lisbeth Dahl, Ingvild Eide Graff, Jannike Øyen, Ive Nerhus and Øyvind Lie
 - RKBU vest, Uni helse: Ingrid Kvestad and Mari Hysing
- Finance
 - The Norwegian Seafood Research Fund - FHF
- Recruitment
 - Women's Clinic, Helse Bergen, Haukeland University Hospital



Aim



Investigate if a regular intake of cod in pregnancy has impact on infant development



Objectives (work packages)

WP 1: Measure iodine levels in a variety of fish species and dairy products

FOOD ANALYSIS

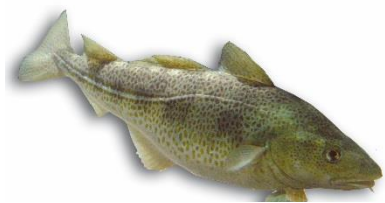
WP2: Does a regular dietary intake of iodine change the iodine status in pregnant?

INTERVENTION STUDY

WP3: Will an increased iodine status in pregnancy be reflected in child development?

FOLLOW UP ON INTERVENTION

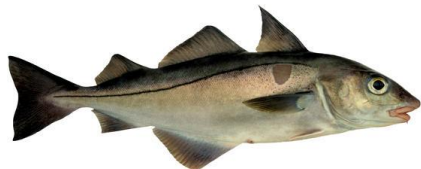
WP 1: FOOD ANALYSIS -Fish



→ ~ 50 samples of each species
→ 1 sample



$\mu\text{g}/100\text{g}$ iodine



WP 1: FOOD ANALYSIS -Dairy



2 analytical paralels

2 analytical paralels

2 analytical paralels

μg/100g iodine

September 2015

December 2015

June 2016



Mammas mat (Mommy's food) WP2 & WP3



Aim and Hypotheses



Aim Investigate if a regular intake of cod in pregnancy has impact on infant development

H₀ Dietary intake of iodine rich food such as cod has no impact on iodine status of mothers in pregnancy and/or infant development

H₁ Dietary intake of iodine rich food such as cod has an impact on iodine status of mothers in pregnancy and/or infant development

Design and main variables



Design

Two armed randomized non-blinded intervention trial

Primary outcome variable

Maternal and infant iodine status

Secondary outcome variable

Neurodevelopment

Subjects



Source population

All pregnant women receiving a summons for the routine ultrasound check-up of their fetus in week 17-19 during the recruitment, ~400 monthly

Inclusion criteria

≤ gestational week 19, primiparous singleton pregnancy, comprehension of Norwegian language

Exclusion criteria

allergies to fish, chronic disease known to affect iodine status (Graves' disease, thyroiditis, thyroid nodules, hypothyroidism, hyperthyroidism)

Power



Based on the following simplified equation

(Institute of Medicine 2001)

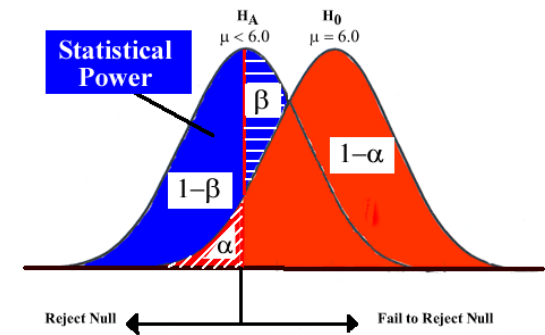
$$UIC / 0.92 \times (0.0009 \text{ L/h/kg} \times 24 \text{ h/d}) \times \text{weight (kg)} = \text{daily iodine intake}$$

and data from the «Little in Norway» cohort

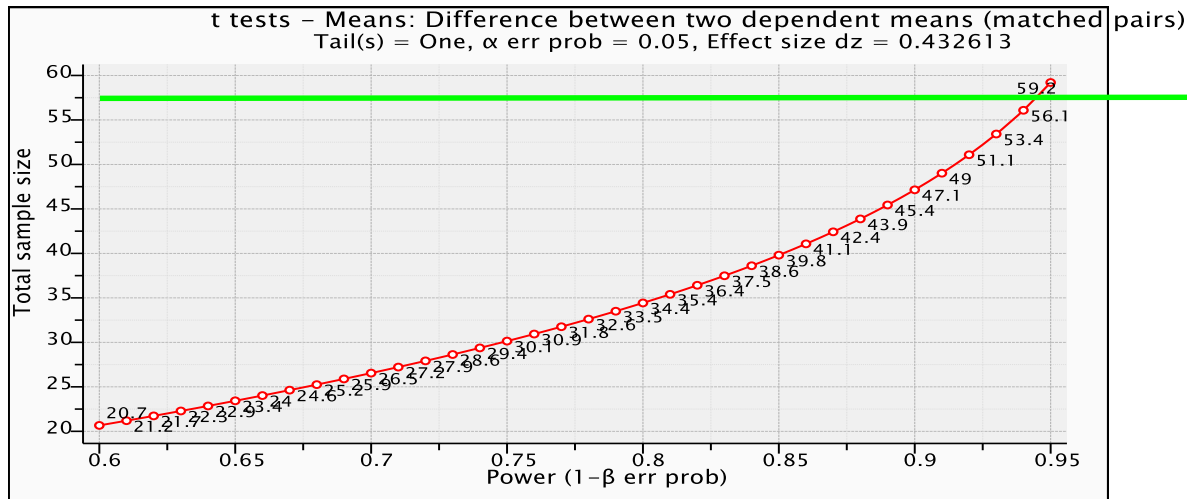
The median UIC was 82 µg/L and the estimated iodine intake was thus 114 µg/day

Power

- 400 grams of cod per week
- ~iodine 100 μg /100 gram
- will increase the mean estimated intake of iodine per week from 800 μg /week to 1200 μg /week



Power



- a sample size of 60 women/group will have a 95% power to detect a 30% higher UIC in the intervention group than in the control group
- taken into account a 20% drop out rate a total sample size of 144, divided into two groups, is anticipated

Recruitment

- All pregnant women in the source population will be given a folder with information regarding the intervention trial together with the date/time for their routine ultrasound, which takes place in gestational week 17-19
- Recruitment has a planned start 1st October 2015
- Intervention will start in December 2015...
- Estimated recruitment for four months...



Data collection - Intervention

Control
n=72



Pregnancy

12 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 36

Birth

Intervention
n=72



Pregnancy

12 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 36

Birth

Recruitment

Pre-sampling

Post-sampling



200 x 2 GRAM COD WEEKLY FOR 16 WEEKS



Sampling



Pre sampling, gestationalweek 19

Biological: UIC (4-6 spot per individual incl. creatinin), thyroid hormone status, fatty acid status, mercury status, iron status

Questionnaires: Short-FFQ, SES & background variables,...

Intervention

Food dairy to record intake of study diet

Post sampling, gestational week 36

Identical to pre sampling



12

01.10.12
Dato: 26.01.2012

Sjematittak
Du vil si igjen til forskersene om spørsmålene dine. Du får 3 nye månedene i tillegg til de du fylte ut tidligere. Med sjematittak er det viktig å være ærlig og beskrive det du faktisk spiser og drikker. Du vil bli kontaktet igjen om du har spørsmål om sjematittaket eller om du har spørsmål om ditt spørsmålene som er sendt til deg. Du vil bli kontaktet igjen om du har spørsmål om ditt spørsmålene som er sendt til deg. Du vil bli kontaktet igjen om du har spørsmål om ditt spørsmålene som er sendt til deg. Du vil bli kontaktet igjen om du har spørsmål om ditt spørsmålene som er sendt til deg.

1. Hvor ofte bruker du fisk, fiskeprodukter eller annen sjematittak som middagssjematittak?
 Alder: 1-2 ganger i uken, 3-4 ganger i uken, 1-2 ganger i måneden, 1-2 ganger i kvartalet, Alder:

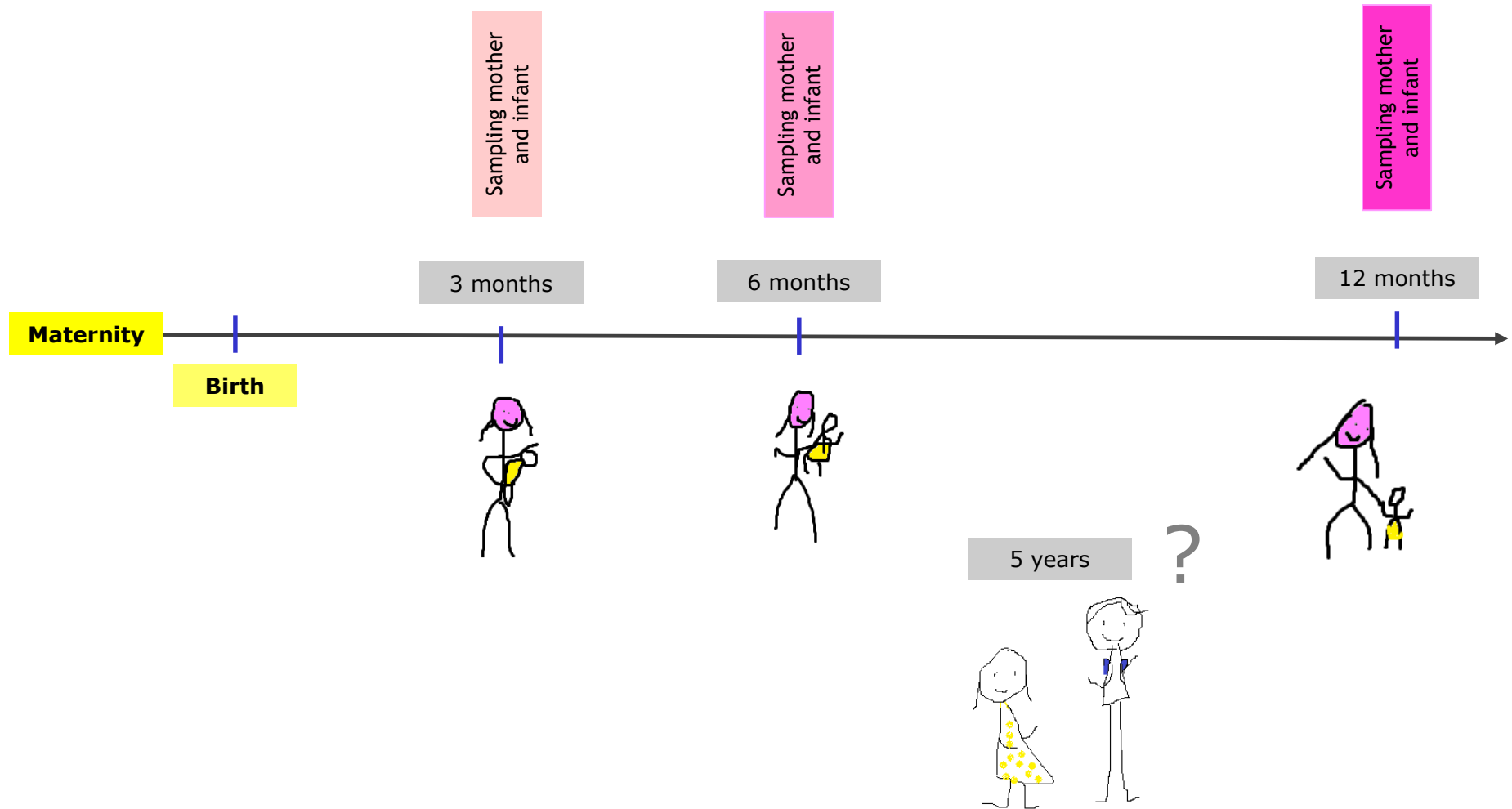
2. Hvis du spiser fisk, fiskeprodukter eller annen sjematittak som middagssjematittak, hvor mye spiser du vanligvis?
 (1 portion = 100 gram, skiver for skje eller 1 fiskekake eller 2-3 raker skive)
 1-2 portioner eller mindre, 3 portioner, 4-5 portioner, 6-7 portioner, Alder:

3. Hvor ofte bruker du sjematittak som pålegg, i salat, mellommåltid, snacks eller lignende?
 Alder: 1-2 ganger i uken, 3-4 ganger i uken, 1-2 ganger i måneden, 1-2 ganger i kvartalet, Alder:

4. Hvis du bruker sjematittak som pålegg, i salat, mellommåltid, snacks eller lignende, hvilken type sjematittak bruker du vanligvis?
 (Hver skje eller biter med sjematittak eller 1 fiskekake eller 2-3 raker skive)
 2. fiskekake, 3. fiskekake, 4. fiskekake, 5. fiskekake, Alder:

26.01.2012

Data collection -follow up



Sampling



3, 6 and 12 months sampling (mother & child)

Biological: UIC (4-6 spot per individual incl. creatinin), thyroid hormone status, fatty acid status, mercury status, iron status, breast milk iodine status (4-6 spot per individual)

Questionnaires: Short-FFQ, SES & background variables, ASQ-SE
24-hour dietary recall (infants)

12 months sampling

Extensive infant development testing (BSID-III ADBB, sleep



12

11-101-
Form: 2.6.01.2017

Hjemsafmåling
Så vil vi gerne få information om spisesituationen din. Du får 3 eller mere måltider i løbet af de 24 timer du lever. Måltiderne består af frokost, aftensmad og eventuelt mellemmåltider. Du kan også have et eller flere mellemmåltider om dagen. Vi er klar over at køkkenet varierer fra dag til dag. Hvis du har et køkken med et eller flere køkkener, er det vigtigt at du angiver hvilke køkkener du bruger. Vi vil gerne vide om du bruger køkkenet til at lave mad til dig selv og/eller til andre. Det er vigtigt at du angiver hvilke køkkener du bruger til at lave mad til dig selv og/eller til andre.

A. Fødevarer eller anden spisetilværelse?

11 gange eller mere	1-10 gange	5-10 gange	1-2 gange	0
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

reproducerer eller anden spisetilværelse?

11 gange eller mere	1-10 gange	5-10 gange	1-2 gange	0
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

spiser som pålæg, i salat, mellemmåltid, snacks eller lignende?

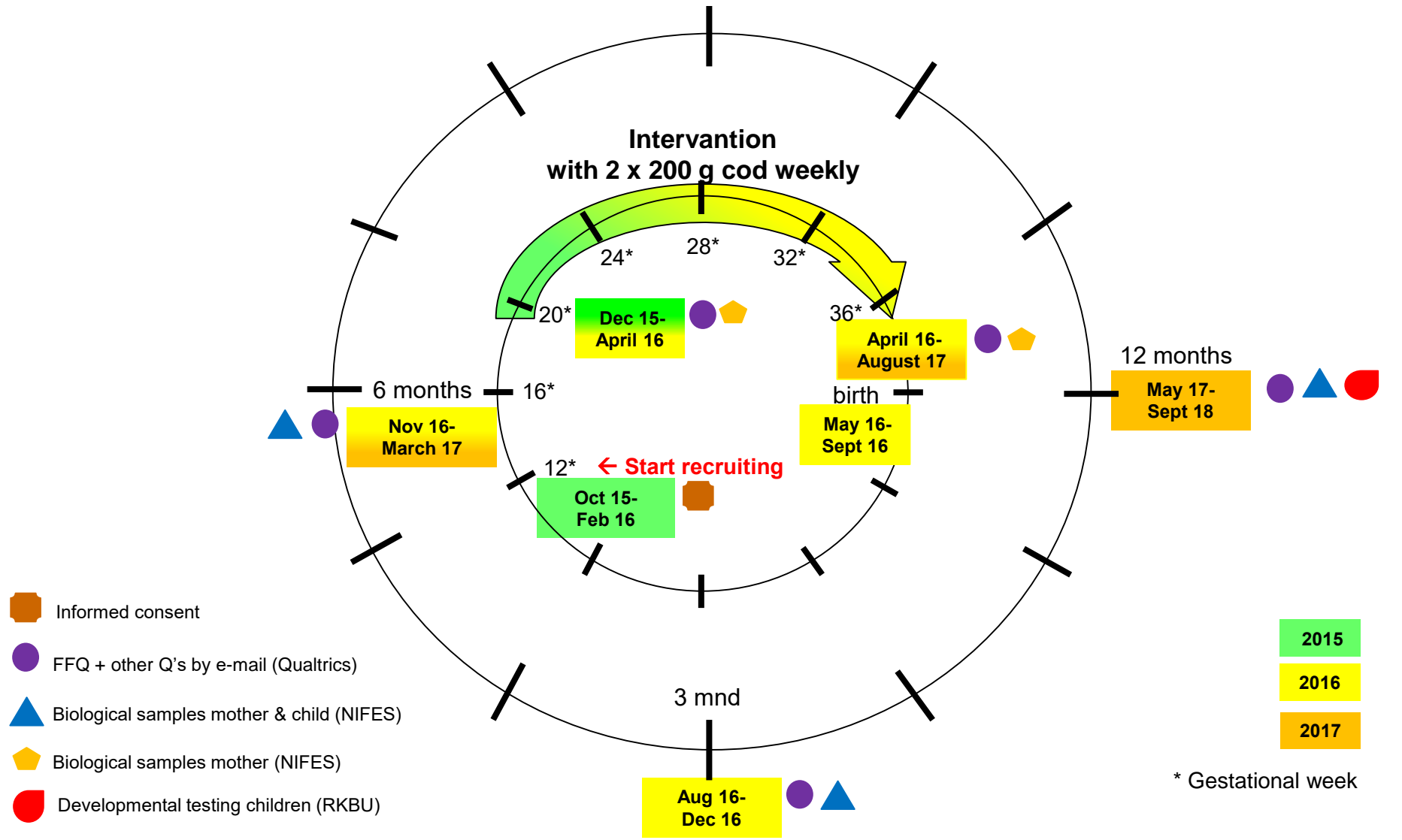
11 gange eller mere	1-10 gange	5-10 gange	1-2 gange	0
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

af som pålæg, i salat, mellemmåltid, snacks eller lignende, vil du spise?

11 gange eller mere 1-10 gange 5-10 gange 1-2 gange 0

11 gange eller mere 1-10 gange 5-10 gange 1-2 gange 0

Timewheel



Analysis & publishing

- Laboratory analysis starts August 2016
- Data analysis starts autumn 2016

- Publishing
 - WP 1: 2016
 - WP 1 and 2: 2017
 - WP 2 and 3: 2018



KEEP
CALM
AND
WAIT FOR
THE RESULTS

