

Mammas mat

Protocol for the study on pregnant women

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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

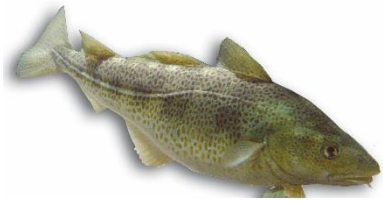
WP2: Does a regular dietary intake of iodine change the iodine status in pregnant?

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)

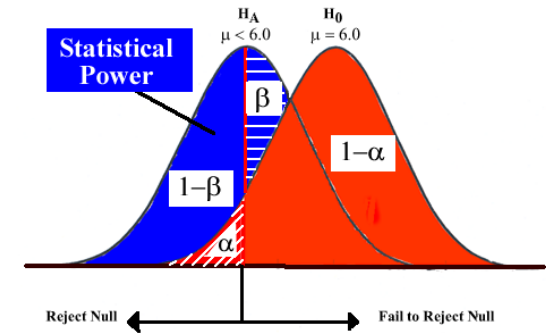
$$UIC / 0.92 \times (0.0009 \text{ L/h/kg} \times 24 \text{ h/d}) \times \text{weight (kg)} = \text{daily iodine intake}$$

and data from the «Little in Norway» cohort

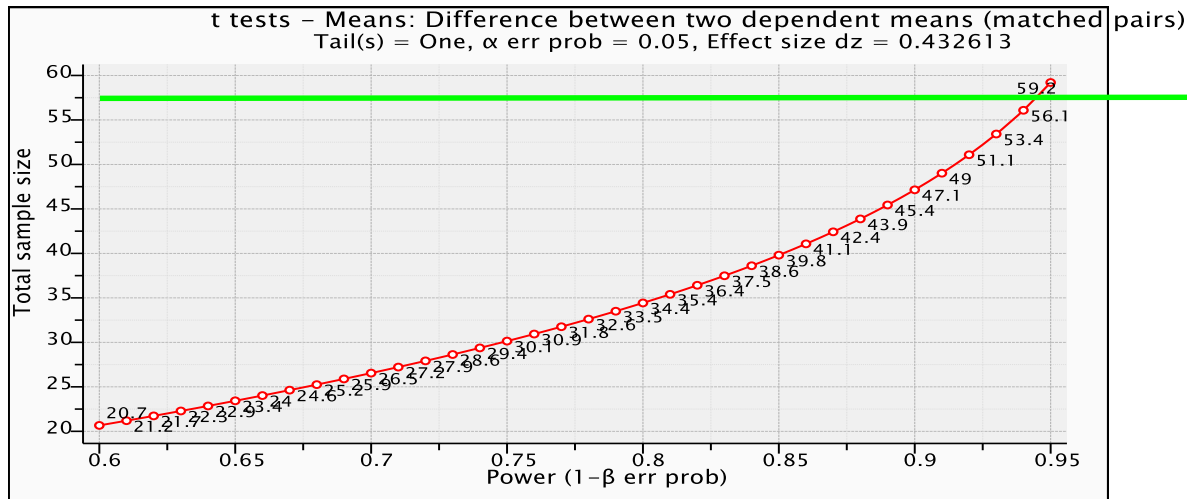
The median UIC was 82 µg/L and the estimated iodine intake was thus 114 µg/day

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

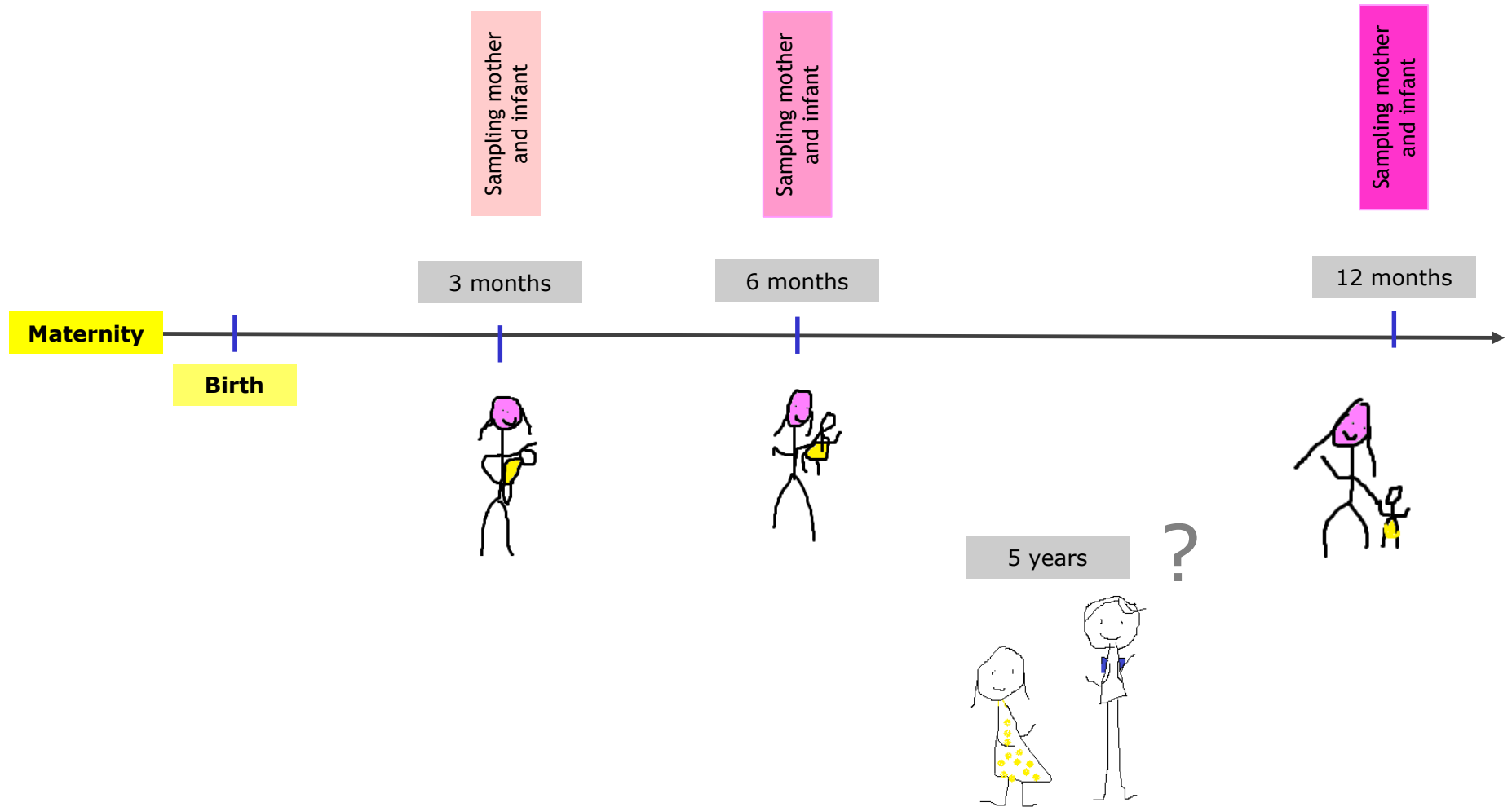
Post-sampling



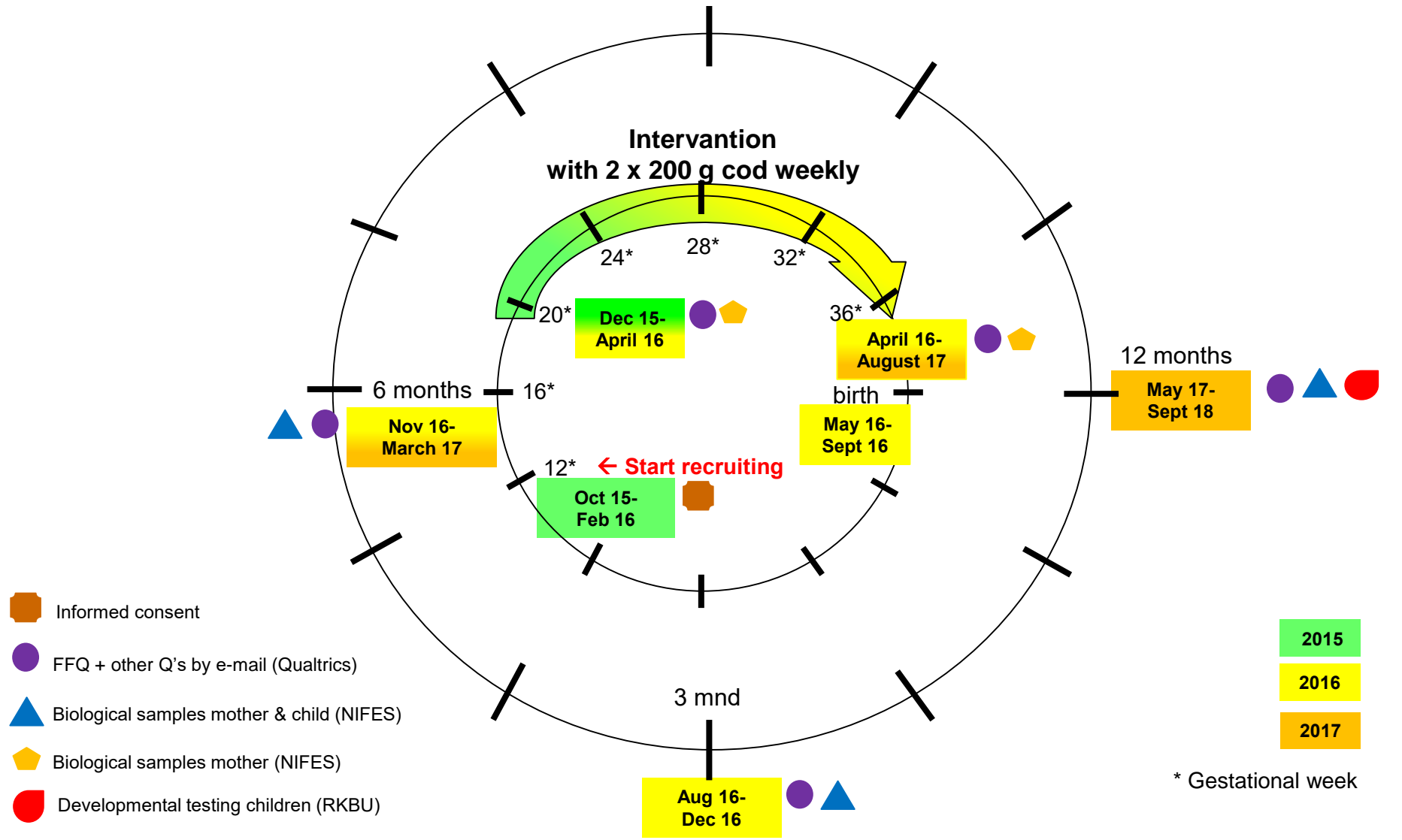
200 x 2 GRAM COD WEEKLY FOR 16 WEEKS



Data collection -follow up



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

