NQPlus - a longitudinal study on diet and health

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To set up NQplus, a longitudinal observational study on 1750 members of the sampling frame to a. build NDARD, the National Dietary Assessment Reference Databaseb. build a database to validate the LifeLines FFQc. build a database and biobank for the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON36462

Source
ToetsingOnline

Brief title
NQPlus

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Lifestyle issues

Synonym
health

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: NWO Investeringssubsidie;ZONMW,EU project

Intervention

Keyword: database, epidemiology, nutrition, questionnaires

Outcome measures

Primary outcome

Dietary intake from 24h recalls and from FFQ;

Carotenoids, fatty acids of erythrocytes as biomarkers of intake, and total en

HDL-cholesterol, triglycerides and glucose from blood as intermediate health

outcomes and to serve the participants;

Capacity to identify specific taste and smell;

Nitrogen, sodium and potassium from urine as biomarkers of intake;

Intermediate health outcomes to be related to aspects of dietaru intake, food

patterns and eating behaviou : BMI, waist-hip ratio, serum lipids, blood

glucose, blood pressure, arterial stiffness, skin fluorescence, cognition

(questionnaire and test), depression (questionnaire), quality of life;

Determinants of dietary intake, food patterns and eating behaviour, to be

studied in relation to relevant health outcomes such as obesity: demographics,

history of illness, medication use, physical activity, aspects of food choice,

smoking habits, stress, sleeping habits, self esteem, sunlight exposure.

Secondary outcome

under these we would like to mentino the measurement which are planned or

enviasegd to be measured in subsamples/substudies:

Dietary intake using duplicate portions;

Energy expenditure using doubly labeled water;

Physical activity using accelerometer;

Fatty acids and RNA in fat biopsy;

Body fatness using MR;.

Microbiota in faeces.

Study description

Background summary

Food Frequency Questionnaires (FFQ) are commonly applied to collect dietary intake information. Ideally, an FFQ is generated using information on dietary intake of a large representative sample. The Dutch FFQ tool now uses information of the Dutch National Food Consumption Survey 1998, but this is not only outdated, it also lacks sufficient information on the individual variation of intake and food patterns. Also, objective information as obtained from biochemical markers is needed to be able to evaluate the occurrence of under- and overreporting.
Furthermore, the FFQ devoped by us for the LifeLines cohort of UMCG needs to be valided.
Finally, the collection of longitudinal data on dietary intake and eating behaviour in a large group of men and women provides the unique opportunity to to study dietary intake, food patterns, and eating behaviour in relation to relevant intermediate health outcomes, such as blood pressure, serum lipids, obesity and cognition. This database will be used for several studies and PhD projects of the division of Human Nutrition.

Study objective

To set up NQplus, a longitudinal observational study on 1750 members of the sampling frame to
a. build NDARD, the National Dietary Assessment Reference Database
b. build a database to validate the LifeLines FFQ
c. build a database and biobank for the study of diet, eating behavior and intermediate health outcomes

In addition, three sub-studies are planned, each with an additional goal:
Sub-study 1 (additional study on energy intake and expenditure, i.e. double portions,m doubly labeled water, and accelerometer) aims at retrieving more detalied and valid information on a sub-samples of NQplus participants regarding dietary intake (through double portion technique,) energy expenditure and intake (doubly labelled water) and physical activity (with accelerometers);
Sub-study 2 (MRI and Fat biopsy) aims to study differences in phenotype between subjects with similar BMI but different fat distibution over the body in a

sub-sample of NQplus participants;
Sub-study 3 (feces collection) aims at studying the variation in bacterial microflora in the gut and relating this to aspects of dietary intake and health (notably obesity).

Study design

Longitudinal observational study in three stages: the 1st stage consists of a short questionnaire send out to 50,000 men and women aged 20-70 yrs of area around Wageningen/Ede (EetMeetWeet, the Sampling Frame, not part of this protocol);
persons willing to participate will be enrolled in NQplus (2nd stage, n=1750) and they will be asked to fill in additional questionnaires on diet, lifestyle and health, and to undergo a short physical examination incl. venapuncture.
When the 2nd stage starts, a specific number of participants will be invited to participate in an additional sub-study (3rd stage).

Study burden and risks

Subjects will be asked for a physical examination three or five times in 48 months, incl. venipuncture and 24-hr urine collection. Half of the group will fill in 13 web-based FFQs over 4 years. They have to collect their urine three times and fill in five web-based dietary recalls. Participating in the second group of 750 subjects means completing nine 24-hr dietary recalls, 3 by phone and 6 web-based, over one year, and three in the last year of the study (1 phone, 2 web-based), and a total of 3 web-based FFQ*s over 4 years. All subjects will be asked to fill in questionnaires on health, behavior and personal characteristics. The questionnaires are clustered in such a way that filling in takes maximally 40 minutes per month and overall max. 120 minutes per year.
Venapunctures can occasionally cause a local hematoma or bruise and some participants may report pain or discomfort.
Measurement of bone mass, fat mass and fat free mass will be done using DEXA. This procedure uses a very low dose of X-ray, comparable to that of skiing or walking half a day in the mountains.
Benefit for the individual participants is that they receive information on their BMI, blood pressure, total and HDL-cholesterol, triglyceride and glucose level, with interpretation based on the guidelines of Dutch GPs (NHG-standaard), and the advice to contact their GP when values are to be considered too high.

For the smaller sub-studies the burden includes possibly (when one decides to participate) collection of double portions for 2 days (costs reimbursed), wearing accelerometer for 7 days and for a small group the drink of doubly labelled water and sampling of 4 spot-urines. Adverse effectsof doubly labelled water have never been reported, they are naturally occuring stable isotopes.

For the sub-study on MRI one should be willing to do this, and also to give a fat biopsy. Subjects with claustrophobia are excluded. A fat biopsy can sometimes give a nasty bruise.
For the sub-study on gut microflora, subjects are asked to collect stool at least once during one week (n=max 500).
Participation to the sub-studies is on voluntary basis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 20-70 yrs
Competent to make own decisions
Written informed consent obtained

Exclusion criteria

Not able to read and speak Dutch

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-07-2011
Enrollment:	1750
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2011
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	21-10-2011
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	11-01-2013
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	

Date:	28-05-2013
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL34775.081.10