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Nutrition Questionnaires and more

Submission date	Recruitment status	[ ] Prospectively registered
06/03/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/04/2018	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/04/2018	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
During the past decades our lifestyle has changed considerably, as shown by for instance a decrease in physical activity levels and changes in dietary habits. With that, the number of people with obesity and cardiometabolic conditions is rising. To pin-point the specific dietary factors that may be responsible for the rise in obesity and adverse cardiometabolic health outcomes, we initiated the Nutrition Questionnaires plus (NQplus) study, a prospective cohort study initiated by researchers of the division of Human Nutrition of Wageningen University. 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 The Dutch FFQ tool now uses information of the Dutch National Food Consumption Survey 1998, but this is not only outdated, it also lacks sufficient information on the individual variation of intake and food patterns.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.

Who can participate?
Men and women, aged 20-70 years, living in the regions Ede, Arnhem, Wageningen, Renkum, Veenendaal en Tiel.

What does the study involve?
This study is a cohort study, so no interventions are involved. Baseline measurements included the assessment of habitual dietary intake (by FFQ and repeated 24-hour recalls), a physical examination (e.g. body composition, blood pressure, tonometry, AGE-measurement, and cognitive performance), venepuncture (taking a blood sample) (e.g. to determine total and HDL-cholesterol, triglycerides, glucose, carotenoids, tocopherols, fatty acids, vitamin D, MGP, and DNA profiles), 24-hour urine collection (e.g. for nitrogen, sodium, and potassium determination), and a variety of validated questionnaires (e.g. on demographics, body weight history, lifestyle, eating behaviour and mental health). All measurements are repeated after one and two years of follow-up.

In the first stage (sampling frame) people are asked to fill in a short questionnaire. In the second stage, subjects will be asked for a physical examination three or five times in 48 months, including venepuncture 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 undergo five web-based

dietary
recalls. Participating in the second group of 750 subjects means completing nine 24-hr dietary recalls, 4 by phone and 5 web-based, over one year, and three in the last year of the study, and a total of 3 web-based FFQs over 4 years.

What are the possible benefits and risks of participating?
Venepuncture can occasionally cause a local hematoma or bruise and some participants may report pain or discomfort. Benefit for the individual participants is that they receive information on their BMI, blood pressure, total and HDL-cholesterol, triglycerides and glucose.

Where is the study run from?
The study was run from Wageningen University & Research, Wageningen, the Netherlands.

When is study starting and how long is it expected to run for?
This study started on 01/07/2011 and finished on 01/04/2015.

How long will the trial be recruiting participants for?
Recruitment lasted from 01/07/2011 to 01/03/2013.

Who is the main contact?
The contact for the NQPlus study is Edith Feskens.

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
NL34775.081.10

Study information

Scientific Title
The Nutrition Questionnaires plus study (NQplus)

Acronym
NQplus

Study objectives
Updated questionnaires and testing provide improved tracking of dietary intake and analysis of relationships with obesity and cardiometabolic disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wageningen University ethics committee, 27/06/2011, NL34775.081.10

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
obesity, cardiovascular disease.

Interventions
The NDARD-project aims to develop a database with dietary data that is collected by means of Food Frequency Questionnaires (FFQs), repeated 24-hour recalls, as well as urinary/blood biomarkers. These data allow the validation and development of new dietary assessment methods, based on methods that provide more information on the variation in dietary intake than the currently used DNFCS database. Hence, it is expected that FFQs generated with this new database will provide more accurate dietary data compared to the FFQs that are currently used.
Given the unique nature of the dietary data collected in view of the NDARD-project, we decided to expand the NDARD-database by collecting extensive data on participant characteristics, including cross-sectional and longitudinal data on demographics, lifestyle, medical history, and (cardio-metabolic) health outcomes: the Nutrition Questionnaire plus (NQplus) study. This study provides the opportunity to explore a large number of interesting research questions related to diet and cardio-metabolic health outcomes using the best dietary intake assessment methods available so far. Associations that can be studied using NQplus data for instance include the potential role of polyphenol intake in relation to blood pressure and arterial stiffness, Na/K excretion in relation to blood pressure, arterial stiffness, and metabolic syndrome, associations between dietary lignans and serum lipids, associations between timing of eating and metabolic health, as well as the association between vitamin D, glucose intolerance, and cognition.
The NQplus study is a large prospective cohort study, primarily conducted among Caucasian Dutch adults aged 20-70 years living in the central part of the Netherlands (i.e. Wageningen and vicinity), initiated as an add-on study to the NDARD-project (Brouwer-Brolsma, submitted for publication). The NQplus study aimed to include 1,750 men and women that were able to speak and write Dutch and competent to make their own decisions. Participants were recruited via: 1) random sampling from the municipality registries of Ede, Wageningen, Renkum (n=30,000), and Arnhem (n=15,000) by sending electronic invitations; and 2) sending invitation letters to all households of Veenendaal (n=25,000). 2,048 men and women were included in the study. Baseline measurements included the assessment of habitual dietary intake by an FFQ and repeated 24-hour recalls, physical examination, venepuncture, 24-hour urine collection, and a

variety of validated health and lifestyle questionnaires. All measurements were repeated at 1 and 2 years of follow-up, and were performed according to a standardized protocol by trained research assistants. All participants gave written informed consent before commencement of the study.

Intervention Type
Behavioural

Primary outcome(s)
1. Dietary intake: Assessment of habitual dietary intake was done by means of an 180-item semi-quantitative FFQ and up to nine repeated 24-hour recalls. All measurements were repeated at one and two years of follow-up.
2. Eating behaviour was assessed by means of the Dutch Eating Behaviour Questionnaire (DEBQ). Additionally, eating behaviour was assessed by a questionnaire developed by research institute Wageningen Economic Research (WECR). The Food Choice Questionnaire (FCQ) was used to assess factors related to food choice. Food neophobia was scored using the Food Neophobia Scale. Eating Rate was assessed according to one of five rating categories. Determinants of intake of fruit vegetables and snacks was examined by means of a questionnaire as developed by Hooft van Huysduynen and colleagues (2014) based on determinants from the Theory of Planned Behaviour. All measurements were repeated at one and two years of follow-up.
3. Nutritional recovery biomarkers: Total 24-hour urinary nitrogen excretion was determined at the Division of Human Nutrition by the Kjeldahl technique 19 (Foss KjeltecTM 2300 analyzer). Urinary sodium and potassium concentrations were measured with an ion-selective electrode on a Roche 917 analyser (Indianapolis, USA). Urinary creatinine concentrations were measured at 520 nm on the Synchron LX20 by the modified Jaffé procedure using a commercial kit. Total 24-hour sodium and potassium excretion were calculated by multiplying total weight of collected urine by sodium or potassium concentration. Additionally, this was divided by 0.86 for sodium and by 0.81 for potassium, assuming that this percentage of intake is excreted in the urine. Urinary protein was calculated with the following formula: 6.25 * (urinary N / 0.81) accounting for faecal and skin losses (approximately 19%). All measurements were repeated at one and two years of follow-up
4. Anthropometrics: Height was measured with a stadiometer (SECA, Germany) to the nearest 0.1 cm. Weight was measured using a digital scale (SECA, Germany) to the nearest 0.1 kg. Waist and hip circumference was measured twice by a non-flexible measuring tape (SECA 201, Germany) to the nearest 0.5 cm; the average of the two measurements was included in the dataset. Prior to measurements, participants were asked to take off their shoes, sweaters and to empty their pockets. All measurements were repeated at one and two years of follow-up
5. Body composition: Body composition (i.e. total fat mass, lean body mass, body fat percentage) and bone mineral density were measured by a Dual-energy X-ray Absorptiometry (DXA) scan (Lunar prodigy, GE healthcare). If a participant did not fit the width outline of the scanner, only the right side of the body was scanned and results were mirrored. In a subsample (n=199), body composition (i.e. total fat, lean body mass, fat percentage) was measured using the Tanita body composition analyser (BC418MA, Tanita Corporation) instead of DXA. All measurements were repeated at one and two years of follow-up.
6. Vascular measurements: After 10 min of rest, blood pressure was measured on the left arm, six times with two minutes rest in between, while the participant was in supine position (IntelliSense HEM-907, Omron Health Care, USA). The second up to the sixth measurement were averaged; the first measurement was omitted to acclimatize the participant to the measurements. Dominant arm and room temperature were recorded. Advance Glycation Endproduct (AGE) accumulation was noninvasively measured in the human skin of the forearm,

with an AGE-Reader (DiagnOptics B.V., Groningen, the Netherlands) on the inner side of the lower arm. Measurements were repeated three times and subsequently averaged. Arterial stiffness was assessed by pulse wave analysis of the radial artery by applanation tonometry (SphygmoCor® system, ATcor Medical, Sydney, Australia). A pressure-sensitive probe was placed on the radial artery to generate a pulse pressure wave. Subsequently, the corrected augmentation index (Aix) is estimated by combining the data of the brachial blood pressure measurements, central aortic pressure measurements, and heart rate measurements. All measurements were repeated at one and two years of follow-up.
7. Fasting blood biomarkers: Total cholesterol, HDL-cholesterol, triglycerides glucose, and creatinine were determined with enzymatic methods. LDL-cholesterol was calculated with the Friedewald equation. Catalytic activity concentration of alanine aminotransferase (ALT), aspartate aminotransferase (AST) and gamma glutamyltranspeptidase (γGT) levels were measured by international federation of clinical chemistry reference procedures at 37 °C degrees. For albumin determinations the bromocresol purple method was used. HbA1c was determined with HPLC measurement technology using an ADAMSTM A1c HA-8160 analyser (A. Menarini Diagnostics). Hb and Ht were assessed with colorimetric measurements using Advia 2120i Automatic analyser (Siemens, Erlangen, Germany) or using Sysmex XNseries (Sysmex inc., Lincolnshire, USA). Erythrocytes and leucocytes, including monocytes and lymphocytes, were determined with flow cytometry (Advia 2120i automatic analyser, Siemens, Germany or Sysmex XNseries, Sysmex inc., USA). An estimated Glomerular Filtration Rate (GFR) was calculated using the Modification of Diet in Renal Disease (MDRD) study equation as well as the new Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. All measurements were repeated at one and two years of follow-up.

Key secondary outcome(s))
N/A

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Able to speak and write Dutch
2. Competent to make their own decisions

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2011

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Wageningen University & Research
Netherlands
6700AA

Sponsor information

Organisation
Wageningen University & Research

ROR
https://ror.org/04qw24q55

Funder(s)

Funder type
Not defined

Funder Name
ZonMw, Grant 91110030, Grant 115100007

Funder Name
NWO, Netherlands Organisation for Scientific Research

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EU (PreView Grant 31 2057, Grant BBMRI-NL RP9 and CP2011-38)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes