The Nutrition Researcher Cohort n250 Study; new standardized self-quantification methodologies serving both research and personal health maintenance

Published: 20-01-2015
Last updated: 13-04-2024

The main goal of the NRC in the planned 2014 study is to develop and evaluate the open access Nutrition Researcher Cohort for gathering personal health data from nutrition researchers, including analytical methods, standards and operation procedures...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41848

Source
ToetsingOnline

Brief title
NRC n250 study

Condition

- Other condition

Synonym
health parameters and biomarkers, nutrition

Health condition

algemeen gezondheidsparameters, biomarkers en voeding

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: In andere deelnemende landen zijn deelnemende universiteiten zelf verantwoordelijk voor de financiering van de opzet van het cohort; daarnaast zal een aantal universiteiten mogelijk een deel van de analyses op zich nemen ,is nog niet bekend,mogelijk zullen commerciële bedrijven hun diensten gratis (bijv. lab analyses of aanbiedien van een optionele zelfkwantificatie methode) aanbieden aan dit cohort,TNO en andere deelnemende instituten en universiteiten;en sponsors van specifieke metingen

Intervention

Keyword: Data Collection, Health, Nutritional Physiological Phenomena, self-quantification methodologies

Outcome measures

Primary outcome

The open access Nutrition Researcher Cohort for gathering personal health data

from nutrition researchers will be evaluated by determining compliance of

participants with the research protocol. Compliance will be determined for

self-quantification methods that all participants are expected to use, as well

as the optional measures. Compliance of participants with the study protocol

will also be compared between countries.

User experiences with participating in the cohort and using

self-quantification methods for monitoring their health will be assessed with a

questionnaire on user-experience after one year. This questionnaire has not yet

been finalized, as it is not yet clear which specific self-quantification

methods will be included in the cohort. However, a format for this

questionnaire has already been developed (F09). The questionnaire will encompass questions on the cohort in general, the used visualisations for personal data, usability of the self-quantification methods, the satisfaction of the user with the self-quantification methods and the effects of self-quantification on user behaviour.

Secondary outcome

Dependent on the quality, the data resulting from the self-quantification methods (including body weight, physical activity, food intake, blood glucose, blood pressure, resting heart rate, quality of sleep, cortisol in hair, epigenetics, etc.) will be analysed to identify changes in these health parameters over time.

These self-quantification methods can be divided into two groups, namely the self-quantification methods that are mandatory for all participants and those that are optional. The first group of self-quantification methods include conventional non-invasive or minimally invasive measures, like body weight, waist circumference, blood pressure, fasting glucose and blood lipids with finger prick. The set of optional self-quantification methods, which are more complex or invasive methods, is not yet set. Which measurements will be offered to participants is dependent on funding. Examples of measurements that could be included are concentrations of biomarkers in blood, cortisol in hair/nail (as a biomarker for stress) clippings and epigenetic profile.

The complete lists of mandatory and optional self-quantification measurements and the can be found in table 1-2, respectively table 3. Table 1 and 2 also contain the procedures that participants should use for each of the included

measurements. Table 3 contains the required laboratory analysis methods and the intended labs.

All subjects will also be asked to regularly fill out online-questionnaires on general health status, lifestyle (smoking, alcohol consumption), quality of sleep, stress, physical activity and quality of life (table 2). Which specific questionnaires will be used in this cohort, has not yet been decided on. However, sample questionnaires have been added to this protocol as an indication for the expected burden for participants (chapter 11).

Study description

Background summary

Healthy nutrition has large potential in reducing risks of diseases like cancer and cardiovascular disease. However, the population-based approaches via which healthy nutrition is stimulated have been largely ineffective. In the past decade, new developments in the application of advanced nutrigenetics technologies, and bioinformatics providing integration of relevant data, have furthered the concept of personalized nutrition, causing a paradigm shift from the mindset of *one-diet-fits-all* to *the right diet for the right person at the right time*. Personalized nutrition could address the current limitations and transform the nutrition research field. The ultimate goal of personalized nutrition is that in the future, each individual is empowered to make personal and sustainable choices on diet that optimally fit her/his health maintenance and lifestyle. This includes access to reliable information on personal health trajectory and status, and the effect of diet(ary changes) on personal health. The Nutrition Researcher Cohort (NRC) aims to build such a *personal health portal* that allows use of anonymized data for research, but also provides all participants with their personal health data as well as dietary advice with personal dietary advice systems based on the individual`s health trajectory. As a basis for this NRC, it is aimed to establish and optimize new standardized methodology of self-quantification serving both research and (personal) health maintenance/optimization.

Study objective

The main goal of the NRC in the planned 2014 study is to develop and evaluate the open access Nutrition Researcher Cohort for gathering personal health data from nutrition researchers, including analytical methods, standards and operation procedures, data infrastructure, ethical and privacy aspects, and governance. This will be measured by compliance of participants with the research protocol, and user experiences concerning participation in the cohort and use of self-quantification methods.

The specific objectives of the NRC in the 2014 study are:
1. To gather data, that is collected by study participants with self-quantification methods, that:
• give an accurate estimate of food intake and exposure to diets and dietary bioactives
• represent robustly measured biomarkers for health and (emerging) risk factors for disease
2. To exploit and analyse data on
• food, nutrient and bioactive compound intake and exposure
• biomarkers for food intake and/or health and/or disease
• health and/or diseases related measurements

In addition, data will be used to develop applications that visualise personal health risks based for example on (validated) recommendations and applications that predict individual health risks. For research purposes the data will be used for collaboration research as well as comparisons.

Study design

The NRC 2014 study is an open, one-group, open-ended cohort study. The NRC cohort 2014 study has already started in Finland. The NRC cohort study in the Netherlands will preferably start in 2014 and continue developing from that moment on. Recruitment will thus start immediately after approval of the study protocol. The Participant Information Form, which contains the complete research protocol as developed by the consortium partners, is available online via the NRC website. This way, potential participants can make an informed decision on whether or not they want to participate.
The NRC 2014 study will provide a dataset of 250 individuals, including food intake, microbiome composition, oral glucose tolerance tests, a series of plasma (bio)chemistry outcomes, plasma and urine metabolome and DNA damage, together with anthropometrics and life style questionnaires.

Since the aim is to build up a powerful open access cohort, there is no end-date defined for this study. However, after one year the NRC cohort will be evaluated. The evaluation of the study concerns the compliance of the subjects with the provided research protocol, as well as their experiences with participating in the cohort. Besides, the collected data will be used for various (descriptive) analyses on food intake, biomarkers for food intake

and/or health and/or disease, and health/disease related measurements.

Study burden and risks

Data collection will be primarily based on *do-it-yourself* non-invasive or minimally invasive methods. These data will be delivered by the participant to the Personal Health Portal. For some health parameters, participants will send their samples to labs for analysis; in this case, the lab will be responsible for uploading the data to the portal. For each health parameter the participant can decide whether or not these data can also be used for research purposes. We do not foresee any health risks in using the do-it-yourself methods for measuring health parameters. All methods have been used in previous studies and most are commercially available, and are therefore, with normal use, considered safe. Data of the study will be uploaded to the online NRC portal by an account created by the study-participant. Personal data and research data are stored in separate databases. Research data is stored pseudonymized, such that researchers that analyse the data cannot connect data to an individual.

Contacts

Public
TNO

Utrechtseweg 48
Zeist 3704 HE
NL
Scientific
TNO

Utrechtseweg 48
Zeist 3704 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Employees or students that are active in the field of nutrition and/or biology and/or health (e.g. epidemiologists, dieticians, nutrition students and researchers) that have a basic knowledge of nutrition and/or human biology and are thus able to form a scientific judgement on his/her own health data;
2. good understanding of the English written language, since all communication is handled in English.

Exclusion criteria

For any participant who matches the inclusion criteria, there are no exclusion criteria. The concept of the Nutrition Researcher Cohort is that research is performed on a *multiple N=1* basis, i.e. each participant provides his/her own health dataset and as such a wide range of healthy and possibly unhealthy subjects can participate. ;In the future, for the proposed research questions suggested by the participants of NRC and agreed in the management of the NRC, a selection may be made including/excluding part of the phenotypes.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2015
Enrollment:	25

Type:	Anticipated

Ethics review

Approved WMO Date:	20-01-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL52069.028.15