European food consumption validation study - Validation of a repeated 24h dietary recall using EPIC-SOFT

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To evaluate the validity of the repeated 24-hour dietary recall method using EPIC-SOFT for assessing food and nutrient intake within countries in Europe, and for comparisons between these countries i.e. to collect data on foods, nutrients and...

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

Summary

ID

NL-OMON30931

Source
ToetsingOnline

Brief title
EFCOVAL study

Condition

- Other condition

Synonym
nvt

Health condition

Geen ziekte-uitkomst

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: 24 hour dietary recall, biomarkers, dietary assessment method, validation study

Outcome measures

Primary outcome

Key foods: Fruit & vegetable intake, Fish & seafood intake

Key nutrients: Protein intake, Fatty acids (EPA, DHA), Potassium intake,

b-carotene intake

Key biomarkers: Urinary nitrogen, Urinary potassium, Serum carotenoids, Fatty

acids in cholesteryl esters

Covariables: Age, gender, BMI, Serum cholesterol

Secondary outcome

Raspberry ketone intake and urinary excretion of raspberry ketone (flavouring

substance)

Lifestyle characteristics: physical activity, eating pattern, use of organic

foods, smoking, supplement use

Food and nutrition intake from food frequency questionnaire

Study description

Background summary

For pan-European nutrition surveys to assess intake at an individual level, the EFCOSUM (European Food Consumption Survey Method) consortium recommends a computerized repeated 24-hour dietary recall method. The European Prospective

Investigation into Cancer and Nutrition (EPIC) research group has developed 24-hour dietary recall software (EPIC-SOFT). This computerized method provides the opportunity to undertake representative nutrition surveys in a standardized manner.

Study objective

To evaluate the validity of the repeated 24-hour dietary recall method using EPIC-SOFT for assessing food and nutrient intake within countries in Europe, and for comparisons between these countries i.e. to collect data on foods, nutrients and biomarkers in five countries with a large variety in food pattern.
Study design: Validation study on assessment of food consumption

Study design

Validation study on assessment of food consumption

Study burden and risks

Participating in the EFCOVAL study means completing four questionnaires, twice being approached for 24-hour dietary recall interviews (both taking about 40 minutes) and collecting two times 24 hour urine accompanied by taking two times three para-aminobenzoic acid (PABA) tablets. Low doses of PABA, as given in methodological studies, have rarely caused any side effects and are therefore regarded as safe. Besides that, one 18 ml blood sample will be taken and height and weight will be measured. In total, the subjects will visit the university only twice, while the other *tasks* can be completed at the home of the subject. After completion of all study procedures, the participant will receive 20 Euros.

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 from 45 to 65 year at the time of recruitment
Apparently health
written informed consent obtained

Exclusion criteria

Unable or unwilling to comply with the study procedures
Having diabetes
Having a kidney disease
Currently taking diuretics
Prescribed medical dietary therapy
Taking antibiotics containing sulphonamides (i.e. sulfadiazine, sulfamethoxazole, sulfametrole and co-trimoxazole)
Hypersensitive to sulphonamides as present in antibiotics (i.e. sulfadiazine, sulfamethoxazole, sulfametrole or co-trimoxazole)
Enrolled in other study in same period
Not able to read or speak Dutch
Pregnant women
Lactating women
Donating blood during the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL16853.081.07