Food4Me Personalised nutrition: An integrated analysis of opportunities and challenges.

Published: 27-04-2012
Last updated: 26-04-2024

The Food4Me study aims to demonstrate the validity of delivering personalised nutrition advice at varying levels in a cohort across 7 EU states:The objective is to challenge the current view that personalised nutrition has to be rooted solely in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39478

Source
ToetsingOnline

Brief title
Food4Me Proof of Principle Study in Personalised Nutrition

Condition

- Other condition

Synonym
personalised nutrition, tailored nutrition

Health condition

nutrition and lifestyle

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: European Union: Seventh Framework Programme

Intervention

Keyword: personalised dietary feedback, personalised nutrition

Outcome measures

Primary outcome

The primary endpoints of the study are the change in eating behaviour,

attitudes towards healthy eating and several body parameters such as weight,

omega3/omega6 fatty acids ratio and vitamin D levels in the blood and the

relation with some genetic variations related to nutrition.

Secondary outcome

N/A

Study description

Background summary

The field of personalised nutrition is relatively new and has not yet been explored in great depth. More work is needed before it can be successfully applied to the general public. Personalised nutrition investigations to date have focused solely on genetic responsiveness to diet. This research intends to conduct a *proof of principal study* by testing the delivery of personalised nutrition at three different levels to determine whether providing more personalised dietary advice leads to better compliance and health outcomes compared to standard population advice. It will be the first study of its kind and aims to produce the state-of-the-art in the area.

The concept of personalised nutrition emerged following the sequencing of the human genome in 2000. It was hoped that with the identification of gene-nutrient interactions, an individual*s response and susceptibility to particular diets would be better understood and therefore appropriate dietary

advice/modifications could be made to optimise health and lower disease risk. Although research in this area (known as nutrigenomics) has deepened and made significant advances, the translation of this knowledge to a sound public health service has not yet been reached. Despite this, the potential of personalised nutrition in advancing public health awareness and delivery is too great to be dismissed without further exploration.
Emerging nutrition research continues to provide convincing benefits for the implementation of personalised nutrition in health care. In the US, the FDA established a Division of Personalised Nutrition within its National Center for Toxicological Research. In the EU, the FP6 funded Network of Excellence NuGo-A (The European Nutrigenomics Organisation) took a global lead in this area, establishing standards for research in the field, promoting concerted research programmes, reaching out to stakeholders and above all, in training a new generation of nutritionists in the application of modern molecular biology to the study of food and health.
Now, that the knowledge has deepened, it is time to test the delivery of personalised nutrition and explore its potential benefit in practice. The translation of such research into a trusted public health nutrition service, built on solid science is central to the present project.

Study objective

The Food4Me study aims to demonstrate the validity of delivering personalised nutrition advice at varying levels in a cohort across 7 EU states:
The objective is to challenge the current view that personalised nutrition has to be rooted solely in genetic responsiveness to diet. It will study the development of a personalised nutrition model at three levels (below), each with more tailored personal advice and determine whether providing more personalised feedback leads to better compliance and health outcomes compared to providing standard population advice:

• Level 0: Control group - will receive non-personalised dietary advice for improved food choice based on standard population healthy eating guidelines
• Level 1: will receive personalised dietary advice for improved food choice based on the analysis of an individual*s current dietary intake;
• Level 2: will receive the same as level 1 with the introduction of using phenotypic data (body and blood biochemistry measurements) in addition to the dietary data for providing more tailored personalised dietary advice;
• Level 3: will receive the same as level 2 with the introduction of using genotypic data (genetic analysis) in addition to the dietary and phenotypic data for providing more tailored personalised dietary advice.

Study design

A detailed overview of the research design is provided in the protocol (page 12)

A total of 160 participants will be recruited and allocated to an intervention group (level 0,1, 2, and 3). These will be further split into a *high or low intensity group* and all will receive a specific level of dietary advice and feedback. Advice will be consistent with healthy eating guidelines and feedback will not be diagnostic. In order to mimic the real-life setting of such a service, the study will be conducted via the internet with postage and telephone calls used where necessary.

Below is an outline of the design:

ACTIVITY HIGH
INTENSITY INTERVENTION (N=80) LOW INTENSITY INTERVENTION (N=80)

Non personalised healthy eating 0, 1, 2, 3
and 6 month 0, 3 and 6 month
guidelines (level 0)

Feedback based on dietary intake 0, 1, 2, 3
and 6 month 0, 3 and 6 month
assessment and PA monitor *
(level 1)

Feedback based on dietary intake 0, 1, 2, 3
and 6 month 0, 3 and 6 month
assessment + PA monitor +
phenotypic assessment ** (level 2)

Feedback based on dietary intake 0, 1, 2, 3
and 6 month 0, 3 and 6 month
assessment + PA monitor +
phenotypic assessment +
genetic characteristics *** (level 3)

* PA: physical activity monitor, provided by Philips
(www.directlife.philips.com)
** Phenotypic assessment refers to body measurements (height, weight, waist, hip and leg circumferences) and blood biochemistry assessment (from finger-prick blood spot samples)
*** Genetic characteristics refers to the measurement of genetic variation relating to nutrition.

Intervention

The delivery of personalised dietary advice will be undertaken by qualified nutritionist in each of the 8 Recruitment Centres. Such dietary advice will be based on different pieces of information depending on group to which the

volunteer is assigned.

ACTIVITY HIGH
INTENSITY INTERVENTION (N=80) LOW INTENSITY INTERVENTION (N=80)

Non personalised healthy eating 0, 1, 2, 3 and
6 month 0, 3 and 6 month
guidelines (level 0)

Feedback based on dietary intake 0, 1, 2, 3 and 6
month 0, 3 and 6 month
assessment and PA monitor *
(level 1)

Feedback based on dietary intake 0, 1, 2, 3 and
6 month 0, 3 and 6 month
assessment + PA monitor +
phenotypic assessment ** (level 2)

Feedback based on dietary intake 0, 1, 2, 3 and
6 month 0, 3 and 6 month
assessment + PA monitor +
phenotypic assessment +
genetic characteristics *** (level 3)

* PA: physical activity monitor, provided by Philips
(www.directlife.philips.com)
** Phenotypic assessment refers to body measurements (height, weight, waist, hip and leg circumferences) and blood biochemistry assessment (from finger-prick blood spot samples)
*** Genetic characteristics refers to the measurement of genetic variation relating to nutrition.

Study burden and risks

A minimal risk is associated with the use of finger-prick blood sampling. However due to the nature of capillary blood, the pin-prick blood clots on average within 30 seconds and heals quickly with minimal discomfort. This is similar to the procedure commonly used at home by diabetics to test their blood glucose levels. It is universally considered safe to be conducted without the presence of medical supervision. A video demonstration will be provided on the website, a hard copy of instructions with debriefing will be provided in the collection pack, along with the contact details of the study investigators should any issues arise.

Subjects will receive healthy eating and lifestyle advice which we expect to be useful to them. In addition, subjects will receive information relating to their health status e.g. cholesterol or blood glucose level, either during or on completion of the study. By participating, subjects will be making a relevant contribution to nutrition research.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects aged above 18 years old

Exclusion criteria

Subjects under 18 years old, pregnant or lactating, no or limited access to the internet, following a prescribed diet for any reason, including weight loss in the last three months, diabetes, celiac disease, Crohn's disease, and major chronic medical conditions requiring continuing intensive therapeutic intervention. Individuals that are not free-living e.g. institutes where meals are prepared.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	184
Type:	Anticipated

Ethics review

Approved WMO Date:	27-04-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-04-2013

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL39135.068.12
Other	Registration was made on clinical trial.org on 19/01/2012 by the leader of the Work Package (NewCastle University). We are still waiting for number