Personalized healthy diet

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21685

Source
NTR

Brief title
PhenFlex 2

Health condition

compromised health, lifestyle related diseases

Sponsors and support

Primary sponsor: TNO
Name – First name: Dijk-Stroeve, Annelies, PhD
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Source(s) of monetary or material Support: PhenFlex 2 consortium;

Intervention

Outcome measures

Primary outcome

The composite biomarker representing “metabolic age” measured at all timepoints during

the PhenFlex drink test day (t=0, 30, 60, 120, 240 min).

Secondary outcome

Metabolic stress markers measured at all timepoints during the PhenFlex drink test day (t=0, 30, 60, 120, 240 min)

The additional effect of personalizing the advice compared to general advice and control, on all markers.

Study description

Background summary

The measurement of health effects of food and nutrients remains a hurdle in the innovation pipeline of many food companies in Europe. Nutrition science has difficulty to demonstrate specific health-beneficial effects related to diet or dietary ingredients. In health research, “optimal health” is increasingly defined in terms of ability to adapt to daily challenges also termed ‘resilience’.

In new concepts of intervention studies, resilience is tested by applying dietary or other challenges, followed by determining the amplitude and recovery time of the responding markers. Useful markers can be combinations of any relevant quantifiable biological parameter resulting in a ‘composite biomarker’. Ultimately, “improved resilience” is thought to become a new EFSA-accepted claimable health benefit of food.

A ‘composite biomarker’ consisting of an integration of PhenFlex challenge responses to glucose, insulin, triglycerides, non-esterified fatty acids, cholesterol, and HDL-cholesterol was defined in a wheat supplementation study that confirmed associated beneficial health effects from epidemiology of wholegrain wheat. In the present study, we would therefore like to test this composite biomarker as a primary outcome to measure metabolic resilience in an already healthy population.

Next to the use of challenges to measure resilience, there is a growing awareness and body of evidence that personalized approaches, both exploiting the individual’s personal health status and motivational aspects, bring additional advantages in optimizing health. The first

scientific studies are being published showing that personalization of dietary recommendations can be beneficial to health. Therefore, in this study an intervention group will be added that will receive personalized dietary recommendations which are fine-tuned to the individual needs based on a series of personal measurements, including e.g. anthropometry, food intake, lifestyle and personality type. This will provide a possibility to investigate if it is possible to extrapolate personal improvements to population level.

The aim of the intervention is to test the efficacy of the proposed new methodology, monitoring response profiles of selected biomarker set as a composite biomarker, in nutrition and health research. Furthermore, we want to show that a personalized lifestyle approach is more beneficial than a generic approach.

Study objective

THypothesis: The integration of measurement outcomes in response to the PhenFlex challenge test will enlarge small, single differences by combining multiple but small effects on metabolism leading eventually to a measurable health difference before and after the intervention and as compared to control.
Main objectove: Demonstrate that a healthy or optimal diet in an intervention study within a healthy population can improve “metabolic age”, which is a composite biomarker quantifying phenotypic flexibility. This composite biomarker validates previous findings from other intervention studies using phenotypic flexibility and could be the next generation biomarker. We want to confirm that ‘metabolic age composite biomarker’ has an added value as compared to evaluation by the single biomarkers it contains.

Study design

before and after dietary intervention

Intervention

A healthy diet personalized to the subject based on individual measurements for nine weeks and a diet based on the general recommended French dietary guidelines.

Contacts

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Eligibility criteria

Inclusion criteria

Males and females aged between ≥25 and ≤70 years at day 1 of the study (limits included);

2. Apparently healthy as assessed by the Health and Lifestyle questionnaire;

3. Body mass index 20-35 kg.m-2 (limits included) (preferably BMI range 25-35 will be included first when possible);

4. Non restrained eater, based on the Three Factor Eating behavior Questionnaire (TFEQ)(15)

5. Able to use online technology on smartphone and a PC/laptop which has good access to the internet;

6. Appropriate veins and circulation for blood sampling according to Biofortis;

7. Good general and mental health according to the investigator: no clinically significant and relevant abnormalities of medical history or physical examination;

8. Able and willing to voluntary participate to the study by complying with the protocol procedures as evidenced by his dated and signed informed consent form;

9. Affiliated with a social security scheme;

10. Women of child-bearing age: with a negative blood pregnancy test and

using a method of contraception, since at least 3 months before the start of the study and deemed effective by the investigator:

-combined (estrogen and progestogen containing) hormonal contraception (oral, intravaginal, transdermal)

-progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable, implantable)

-intrauterine device (IUD)

-intrauterine hormone-releasing system (IUS)

-bilateral tubal occlusion

-Hysterectomy,

-ESSURE system

-vasectomized partner;

11. Agree to be registered on the volunteers in biomedical research file.

Exclusion criteria

1. Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before day 1 of this study;

2. Participation in any non-invasive clinical trial up to 30 days before day 1 of this study, including no blood sampling and/or oral, intravenous, or inhalatory administration of substances;

3. Having a history of medical or surgical events that may significantly affect the study outcome, including more than five years of cardiovascular disease or hypertension or more than two types of medication for CVD or hypertension;

4. Having a history of food allergies or intolerances for nutrients/nutritional components such as lactose, nuts, etc;

5. Having a gastrointestinal disease such as celiac disease, Chron¡¯s disease, inflammatory bowel disease;

6. Having chronic diseases such as metabolic syndrome, chronic

obstructive pulmonary disease (COPD), diabetes mellitus and inflammatory diseases

7. Using prescribed medication or taking painkillers on a regular basis (judged by the medical investigator); medication for CVD is allowed when not more than 2 types of medication are used;

8. Smoking (irregular smoking in the weekend is allowed) *;

9. Being pregnant or lactating;

10. Alcohol consumption: more than 3 standard drinks of alcoholic beverage for men or 2 standard drinks daily for women;

11. Reported unexplained weight loss or gain > 5% of body weight in the 3 months prior to the pre-study screening;

12. Reported slimming or (medically) prescribed diet;

13. Reported vegan, macrobiotic, paleo, raw food, intermittent fasting, Atkins, regular consumption of superfoods, a diet conviction; vegetarians are not excluded;

14. Being regular users of dietary supplements (supplementation can have a negative effect on the intervention);

15. With a personal history of anorexia nervosa, bulimia or significant eating disorders according to the investigator;

16. Not willing to give up blood donation during the study;

17. Donation of blood in the 3 months preceding the study

18. Donation of blood during the study up to 3 months after the end of the study

19. Personnel of Biofortis, their partner and their first and second degree relatives;

20. Taking part in another clinical trial or being in the exclusion period of a previous clinical trial;

21. Having received, during the last 12 months, indemnities for clinical trial higher or equal to 4500 Euros;

22. Under legal protection (guardianship, wardship) or deprived from his rights following administrative or judicial decision;

23. Presenting a psychological or linguistic incapability to sign the informed consent;

24. Impossible to contact in case of emergency.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2018
Enrollment:	165
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	15-05-2018
Application type:	First submission

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
NTR-new	NL7054
NTR-old	NTR7259
Other	CPP (Comités de protection des personnes) : 2018-A00375-50

Study results