# Personalized healthy diet

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| **Ethische beoordeling** | Positief advies |
| **Status** | Anders |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON23314

**Bron**
NTR

**Verkorte titel**
PhenFlex2-Bis

**Aandoening**

Challenge test, phenotypic flexibility, resilience, health, metabolic syndrome

### Ondersteuning

**Primaire sponsor:** PhenFlex2 consortium
**Overige ondersteuning:** TKI AgriFood and consortium partners

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The composite biomarker representing “metabolic age” measured at all timepoints during the PhenFlex drink test day (t=0, 30, 60, 120, 240 min) at visits V1, V2 and V3.

Variables included in the composite biomarker:
Cholesterol, HDL-cholesterol, NEFA, glucose, Insulin, triglycerides
The combined data will be used in a health space model and will provide the composite marker ‘metabolic age’. The metabolic age outcomes before and after the interventions will be compared as well as to the control.
The primary endpoint compares the calculated difference of metabolic age between the intervention group and control group.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

The measurement of the 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 the 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 the 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 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 studied that will receive personalized dietary recommendations that 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 the population level.

The aim of the present intervention is to test the efficacy of the proposed new methodology, monitoring response profiles of the 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 the habitual control lifestyle.

### Doel van het onderzoek

The hypothesis is that the metabolic age, representing a health score will be lower after nine weeks of personalized dietary intervention compared to the control arm (without dietary advice). The phenotypic flexibility or resilience (the ability to adapt) is here defined as the individual physiologic response to a challenge meal and is represented by the composite biomarker “metabolic age”. The ‘metabolic age’ biomarker allows for quantification of phenotypic flexibility, which has been validated by previous findings including results from intervention studies using phenotypic flexibility and could therefore be the next generation biomarker for health assessment.

### Onderzoeksopzet

Three test days; V1 baseline measurement to contain all variables to enable randomization. V2 is the test day at the start of the intervention and V3 the final test day after the intervention. On all test days a Phenflex shake is drunk and blood will be collected before and at 30, 60, 120 and 240 minutes after start of consumption.

### Onderzoeksproduct en/of interventie

An optimal diet based on dietary guidelines related to personal habits and preferences and based on individual measurements (data from FFQ) for nine weeks. The study objectives assessment required that all subjects consume a challenge meal, (the Phenflex drink) at V1, V2 and V3 visits.

## Contactpersonen

### Publiek

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

To be eligible to the study, male and female volunteers will have to fulfill the following criteria (assessment based on the medical examination performed at V0):
1. Males and females aged ≥45 years old;
2. Apparently healthy as assessed by the Health and Lifestyle questionnaire;
3. Body mass index 25-35 kg.m-2 (lower limit excluded and upper limit included);
4. Non restrained eater, based on the Three Factor Eating behavior Questionnaire (TFEQ), the eating factor 1 should be ≤131,2;
5. Presenting at least 2 aspects of metabolic syndrome according to NCEP ATP III (revision 2005) criteria:
- Waist circumference ≥ 88 centimeters for women and ≥ 102 centimeters for men (this one is not applicable now when subjects have a BMI between 25-35 kg/m2);
- Blood triglyceride level ≥ 1.7 mmol/L,
- HDL cholesterol level ≤ 1.04 mmol/L for men and ≤ 1.3 mmol/L for women,
- Blood pressure ≥ 130/85 millimeters mm Hg,
- Fasting blood sugar ≥ 5.6 mmol/L.
6. Able to drink the Phenflex drink (± 25% of the complete volume) and indicating that he/she will be able to consume a whole drink during the visits;
7. Able to use online technology on tablet and a PC/laptop which has good access to the internet;
8. Good general and mental health according to the medical investigator: no clinically significant and relevant abnormalities of medical history or physical examination;
9. 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;
10. Affiliated with a social security scheme;
11. 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;
12. Agree to be registered on the volunteers in biomedical research file.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Participation in any clinical trial up to 30 days before day 1 of this study;
2. Participation in the previous Phenflex clinical trial: IDRCB 2018-A00375-50;
3. Suffering from a metabolic disorder such as diabetes mellitus, Cushing syndrome, thyroid disease, familial hypercholesterolemia;
4. Suffering from a severe chronic disease (e.g. cancer, HIV, renal failure, hepatic or biliary disorders ongoing, chronic inflammatory digestive disease, arthritis or other chronic respiratory trouble, etc.) or gastrointestinal disorders found to be inconsistent with the conduct of the study by the investigator (e.g. celiac disease),
5. Suffering from an uncontrolled hypertension (systolic blood pressure ≥ 160 mmHg and/or diastolic blood pressure ≥ 100 mmHg),
6. Under cholesterol and/or lipid-lowering treatment (e.g. statins, fibrates, ezetimibe, bile acid sequestrants, niacin, etc.) or stopped for less than three months;
7. Prohibited medication: antidiabetic, lipid lowering treatment and some antihypertensive treatment (ß-blocking agents ; thiazide diuretics) ; corticosteroids ; antipsychotics (eg. clozapine, olanzapine) ; antidepressives ; Protease inhibitors ; anti-epileptics, calcineurine inhibitors; including cyclosporine and tacrolimus;
8. 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;
9. Being physically active for more than 5 hours/week;
10. Having a history of food allergies or intolerances for nutrients/nutritional components such as lactose, nuts, etc;
11. Having chronic diseases such as chronic obstructive pulmonary disease (COPD), diabetes mellitus and inflammatory diseases;
12. Using prescribed pain medication or taking painkillers on a regular basis (judged by the investigator);
13. Smoking (irregular smoking in the weekend could be allowed to 10 cigarettes/day maximum);
14. Being pregnant or lactating or have a wish to become pregnant in the coming months;

15. Inappropriate veins and poor blood circulation for blood collection according to the investigator ;
16. Alcohol consumption: more than 3 standard drinks of alcoholic beverage for men or 2 standard drinks daily for women;
17. Reported unexplained weight loss or gain > 5% of body weight in the 3 months prior to the pre-study screening;
18. Reported slimming or (medically) prescribed diet;
19. Reported vegan, macrobiotic, paleo, raw food, intermittent fasting, Atkins, regular consumption of healthy food (food enriched with vitamins, minerals, antioxidants), a diet conviction; vegetarians are not excluded;
20. Being regular users of dietary supplements (supplementation can have a negative effect on the intervention);
21. With a personal history of anorexia nervosa, bulimia or significant eating disorders according to medical history from the subject;
22. Not willing to stop blood donation during the study;
23. Donation of blood in the 3 months preceding the study;
24. Donation of blood during the study up to 1 month after the end of the study;
25. Personnel of Biofortis, their partner and their first and second degree relatives;
26. Having received, during the last 12 months, indemnities for clinical trial higher or equal to 4500 Euros;
27. Under legal protection (guardianship, wardship) or deprived from his rights following administrative or judicial decision;
28. Presenting a psychological or linguistic incapability to sign the informed consent;
29. Impossible to contact in case of emergency.

# Onderzoeksopzet

## Opzet

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|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Placebo |

## Deelname

Nederland

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| Status: | Anders |
| (Verwachte) startdatum: | 11-02-2020 |
| Aantal proefpersonen: | 110 |
| Type: | Onbekend |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies

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| Datum: | 11-02-2020 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8370 |
| Ander register | CPP in France : PEC19011 |

## Resultaten

**Samenvatting resultaten**
- Stroeve, J. H. M., van Wietmarschen, H., Kremer, B. H. A., van Ommen, B. & Wopereis, S. Phenotypic flexibility as a measure of health: the optimal nutritional stress response

test. Genes Nutr. 10, 13 (2015).
- van Ommen, B. & Wopereis, S. Next-Generation Biomarkers of Health. e tl t . Inst. Workshop Ser. 84, 25–33 (2016).