Growing Old Together.

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Primary Objective: To examine whether an intervention of dietary restriction and exercise can bring the phenotypic profiles (with respect to biomarkers of longevity) of normative ageing individuals towards their healthy aging partners (offspring of...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27183

Bron
Nationaal Trial Register

Verkorte titel
GOT

Aandoening

glucose metabolism, lipid metabolism, RNA expression, anthropometrics, body composition, blood pressure, cognitive functioning, physical functioning, resting metabolic rate, depression, quality of life, sleep, hunger and appetite

Ondersteuning

Primaire sponsor: Leiden University Medical Center and Wageningen University
Overige ondersteuning: Netherlands Genomics Initiative (NGI)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in fasting insulin level.

Toelichting onderzoek

Achtergrond van het onderzoek

Caloric restriction (CR) is the most effective intervention known to improve age-related health and to slow the aging process, resulting in an increase in both average and maximum lifespan. This has already been shown in a variety of species as diverse as yeast, worms, fish, flies and rodents. From the perspective of human aging these observations are interesting, but the evidence on the effectiveness of caloric restriction on biomarkers of healthy aging in humans is limited. In the Leiden Longevity Study (LLS) we have two groups of individuals to compare in this sense: a healthy ageing group (members of long-lived families) that display a beneficial profile of many metabolic markers and a normative ageing group (the partners of these members) with an average metabolic profile. The longevity families were included by selecting for living nonagenarian sibships (sibpairs or larger sibships) and recruiting these individuals, their offspring and the partners of that offspring. Thus, the LLS harbours a contrast between longevity family members showing many beneficial phenotypes resembling those induced by CR as compared to their partners as controls, although fat intake and BMI do no differ between these groups. Also contrasts in several metabolic outcomes in favour of offspring of long-lived siblings as compared to their partners (controls) have been shown, making this a unique/distinctive study population to examine the effects of CR, in combination with physical exercise, on several biomarkers of healthy aging. It is hypothesized that after the combined CR/exercise intervention the partners closer resemble metabolic outcome variables of the offspring. We intend to include 70 couples (aged <=75 years) from the LLS without diabetes and with a BMI >=23 and <=35 kg/m2, each consisting of an offspring from long-lived siblings (cases enriched for familial longevity) and his/her current partner. They all participate in a 3 months intervention with 25% lowered energy expenditure by 12.5% caloric restriction and 12.5% more exercise, which will be achieved by setting up individual guidelines according the Dutch guidelines for a healthy diet and based on each subject's habitual dietary habits and physical activity pattern. The primary outcome measure is the change in fasting insulin level. Secondary outcome measures are blood parameters (metabolic/metabolomics), parameters measured in biopsies of muscle and fat (transcriptomics/proteomics/epigenetics), anthropometrics, body composition, blood pressure, 24-hour glucose monitoring, energy metabolism (resting metabolic rate), MR imaging (leg, brain, cartilage of the knee) and psychological factors (cognitive performance, mood, quality of life, sleep, hunger).

Doel van het onderzoek

Primary Objective:

To examine whether an intervention of dietary restriction and exercise can bring the phenotypic profiles (with respect to biomarkers of longevity) of normative ageing individuals towards their healthy aging partners (offspring of families with exceptional longevity).

Secondary Objective(s):

1. To examine if such an intervention could still improve the phenotypic profile of the offspring;

2. To examine which (clinical, biochemical, molecular) baseline mediators determine response to treatment.

Onderzoeksopzet

Week 0 and week 13. Anthropometrics and hunger and appetite ratings monthly during the intervention.

Onderzoeksproduct en/of interventie

3 months (13 weeks) intervention with 25% lowered energy expenditure, of which half (12.5% of energy) through caloric restriction and the other half through an increase in physical activity.

Partners of participants will serve as a control group.

Contactpersonen

Publiek

Wageningen University, Division of Human Nutrition
P.O. Box 8129
Ondine Rest, van de
Wageningen 6700 EV
The Netherlands
+31 (0)317 485867

Wetenschappelijk

Wageningen University, Division of Human Nutrition
P.O. Box 8129
Ondine Rest, van de
Wageningen 6700 EV
The Netherlands
+31 (0)317 485867

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Middle-aged (≤75 years) couples consisting of offspring from long-lived siblings and his/her current partner or in incidental case as single participant;

2. BMI ≥23 and ≤35 kg/m2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Type I or type II diabetes (on diabetic medication);

2. Individuals who have lost or gained ≥3 kg over the past 6 months;

3. Individuals engaged in heavy/intensive physical activity (top sport or physically heavy work);

4. Any disease or condition that seriously affects body weight and/or body composition including active types of cancer, heart failure (NYHA III/VI), COPD (GOLD III/VI);

5. Recent (3 months prior to intervention) immobilisation for longer than 1 week;

6. Psychiatric or behavioural problems (eg, history or clinical manifestation of any eating disorders, vegan dietary lifestyle, major depression);

7. Medication: thyroid medication, immunosuppressive drugs (e.g. prednisone, methotrexat, biologicals (TNF-alpha antagonists etc);

8. Concurrent participation in any other intervention study or weight management program;

9. Exclusion for biopsy: use of anticoagulantia (e.g. coumarines, carbaspirin calcium);

10. Exclusion MR imaging (7 tesla):

A. Claustrophobia;

B. Pacemakers and defibrillators;

C. Nerve stimulators;

D. Intracranial clips;

E. Intraorbital or intraocular metallic fragments;

F. Cochlear implants;

G. Ferromagnetic implants (e.g. thoracic implant for scoliosis);

H. Inability to lie supine during for 45 minutes;

I. not having a general practitioner

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-03-2012
Aantal proefpersonen:	140
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-06-2012
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	NL3301
NTR-old	NTR3499
Ander register	CME LUMC : P11.187
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A