Growing Old Together.

No registrations found.

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

Summary

ID

NL-OMON27183

Source
NTR

Brief title
GOT

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center and Wageningen University
Source(s) of monetary or material Support: Netherlands Genomics Initiative (NGI)

Intervention

Outcome measures

Primary outcome

Change in fasting insulin level.

Secondary outcome

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).

Study description

Background summary

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).

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2012
Enrollment:	140
Type:	Actual

Ethics review

Positive opinion

Date:	27-06-2012
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	NL3301
NTR-old	NTR3499
Other	CME LUMC : P11.187
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A