Vitality Oriented Innovation for the Lifecourse of the Ageing Society - Intervention Study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54190

Source
ToetsingOnline

Brief title
VOILA

Condition

- Other condition

Synonym
Ageing, getting older

Health condition

veroudering (immunometabool, darmgezondheid, spiergezondheid/functioneren)

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW,Campina,FrieslandCampina

Intervention

Keyword: aging, exercise, intervention, nutrition

Outcome measures

Primary outcome

The main study endpoints are the intervention effects on metabolic outcomes (glucose, glycoprotein acetyl, very low-density lipoprotein diameter), faecal bifidobacterial count, time for the 5-times chair stand test and appendicular lean mass in the intervention groups.

Secondary outcome

The secondary study parameters are:

- Muscle function: Short Physical Performance Battery (SPPB), Timed Up and Go test (TUG), 6-minute walking test (6MWT), 1 repetition maximum test (1RM) as measured on exercise machines
- Body composition: DEXA whole body and regional lean and fat mass
- Immuno-metabolic health: haemoglobin A1c (Hba1c), insulin, blood pressure
- Specifically for the TKR group, additional measures will be performed to assess muscle mass and overall functioning following TKR-surgery: a single-slice CT-scans midway the upper legs, and the Western Ontario and McMaster Universities Arthritis Index (WOMAC).
- Response heterogeneity (and potential explaining factors) will be studied using the above primary and secondary parameters and may be studied in the

future in RNA expression, DNA methylation as well as the influence of genetic variation in the metabolically impaired groups and the reference group and be compared with such studies in other lifestyle interventions in older adults .

Study description

Background summary

Age is the most prominent risk factor for common diseases and multi-morbidity. And yet it is the biological age of individuals even more than their chronological age that influences such risk. The diversity in functioning within the population of older adults suggests that various factors influence biological age, resulting in substantial differences in (patho)physiological state and disease risk between individuals of the same chronological age (heterogeneity). Prominent drivers of biological age have been found in pathways of energy metabolism and balance (metabolic health), chronic inflammation and immunity and a central role for muscle and gut health influencing biological age. Mobility is a major determinant of these drivers and the physiological state of older people.
Combined lifestyle interventions are expected to beneficially influence multiple aspects of biological age but the large heterogeneity of older adults often obscures the effect of interventions. Hence, in order to slow down the biological ageing process via preclinical or clinical interventions, it is necessary to first study the effect of human interventions on diverse health segments of older adults as well as individual older adults. This would allow for a better understanding of biological factors that explain the heterogeneity in responses often observed and could eventually lead to interventions better tailored to segments and individuals.

Study objective

With our proposed multimodal human lifestyle intervention study, containing dietary and exercise components, we aim to improve (combinations of) immuno-metabolic health (blood glucose, glycoprotein acetyls, very low density lipoprotein diameter), gut-health (bifidobacteria), muscle mass (appendicular lean mass) and physical functioning (5-times chair stand test) in three different segments of older adults with varying degrees of compromised mobility or metabolism (>=60 years of age), to study the difference in responsiveness between mobility segments and heterogeneity in responsiveness of individuals both within and between mobility segments.

Study design

The parallel, partially random (only in TKR groups) intervention will have a duration of 12 weeks and includes 3 different intervention groups of older adults segmented primarily by functional and metabolic status, a control group of the knee replacement segment, and an active, community-dwelling reference group representing the healthiest older adults.

Intervention

The intervention consists of a combined exercise and nutritional intervention. All participants will perform 12 weeks of supervised whole-body resistance type exercise training; leg press, leg extension, calf raises, chest press, shoulder press, horizontal row and vertical lateral pull exercise will be performed on weightlifting machines, 3 days per week. The dietary intervention aims to attain a diet that comprises sufficient protein (1.5 g/kg bodyweight/day, distributed as 25-30 g protein per main meal, as well as a pre-sleep intake moment), vitamin D (800 IU/day), calcium (366 mg/day), and prebiotics and is otherwise in line with the Dutch Healthy Diet guidelines. To this end, participants will receive nutritional counselling and will ingest a protein-vitD-calcium-prebiotic product with breakfast, and a protein-calcium product before sleep.

Study burden and risks

The intervention groups perform a supervised resistance type exercise program three times per week, ingest nutritional prototypes twice daily and implement adjustments of the general diet to increase protein intake and adhere to general healthy eating guidelines for a total intervention period of 12 weeks. These types of diets combined with exercise generally benefit muscle, gut and immuno-metabolic health in older adults and have been assessed to be safe in general. People for whom this is contraindicated (e.g. with kidney disease) are excluded. Exercise training bears small risks of injury which will be mitigated by employing trained professionals and executed one-to-one or in small groups suitable to the populations, with individual adjustment of the intensity of the program. It is possible that participants may experience light muscle soreness induced by unaccustomed exercise, especially at the start of the program.
All groups will have the following measurements taken thrice (screening, baseline and endpoint measurements): fill out questionnaires and undergo venepunctures for blood samples, weight and height measured. The following will be collected twice (baseline, endpoint): collect stool samples, wear accelerometers, fill out a dietary record, have their waist circumference measurement taken, perform physical function tests, receive a dual X-ray absorptiometry scan, have their blood pressure taken and fill in several questionnaires. The risk of complications from drawing blood is small and samples will be drawn by trained professionals. There are no complications associated with the procedure of a DXA scan. The level of radiation emitted during a DXA is merely a fraction of that emitted during a regular chest X-ray.

All other measurements take time but are not associated with any risks and will be done under supervision.*

Contacts

Public
Leids Universitair Medisch Centrum

Einthovenweg 20
Leiden 2333ZC
NL
Scientific
Leids Universitair Medisch Centrum

Einthovenweg 20
Leiden 2333ZC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

All participants: age 60 or older, body mass index 18.5-35.0 kg/m2, community-dwelling, mentally competent (MMSE score 24 or over). Depending on the group the main additional criteria are: 1) metabolically compromised group: Metabolomic Mortality Score within the top half of the batch of subjects 60 years and older from and also outside the LLS cohort 2) mobility compromised group: using a walking aid and/or slow 5-times chair stand test (>15 seconds) 3) total knee replacement groups (intervention group and control group): living in/or around the areas of Maastricht, Eindhoven, and Venlo/Roermond/Nijmegen and underwent elective total knee replacement surgery ~6 weeks before start of

study 4) healthy active reference group: meeting the Dutch norms for being physically active, Metabolic Mortality Score below the top half of of the batch of subjects 60 years and older from and also outside the LLS cohort

Exclusion criteria

Already using prebiotic fibres or high doses of supplements, contraindications for using milk/lactose/calcium/vitamin D, engagement in intense physical activity, (aforementioned criteria are not exclusion criteria for the reference group), eGFR <30 ml/min/1.73 m2, diseases, conditions or disorders which may affect the ability to follow the study protocol and which cannot be overcome with help of a caregiver, current participation in other scientific research that conflicts with this study, Not signed up to a general practitioner, No permission to request information from the general practitioner/ treating specialist(s) about medical history, medication use

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2022
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2021

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	27-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	21-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	11-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	21-07-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	27-02-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT05354310
CCMO	NL76879.058.21