The effect of personalised diet and lifestyle advice on muscle health among independently living seniors * a pilot study*

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42412

Source
ToetsingOnline

Brief title
Personalised Advice for healthy Muscles

Condition

- Other condition

Synonym
muscle function, muscle power

Health condition

spiergezondheid

Research involving

Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Ministerie van Economische Zaken

Intervention

Keyword: Community-dwelling seniors, Diet and lifestyle advice, Muscle health, Personalisation

Outcome measures

Primary outcome

On a weekly basis, participants will be asked to score the degree of compliance with the received advice on a 10 cm unstructured line scale with two anchors on 10% and 90% of the scale (very low and very high). By monitoring the degree of implementation during the intervention period, both trends within individuals and between groups can be observed.

Furthermore, the degree of compliance with the advice can be assessed based on dietary intake data as registered in the 'Eetmeter' (an online food diary developed by the 'Dutch nutrition centre'), and the results of the activity tracker.

Secondary outcome

In addition, physical performance, handgrip strength, sedentary behaviour, quality of life, parameters of metabolic health status, protein and lipid profiles in responses to a challenge test, parameters of glycaemic control and patient specific complaints will be measured both at baseline and end.

Study description

Background summary

A healthy diet with adequate protein and energy content and regular physical exercise have been shown to limit and treat age-related declines in muscle mass, strength, and functional abilities. Improving diet and lifestyle behaviours in view of optimizing muscle health requires behaviour change strategies. Previous studies have shown that personalized feedback and advice are more effective than giving general information for improving dietary patterns and increasing physical activity.

Study objective

In the current pilot-study, we will focus on demonstrating whether personalisation improves compliance with advice on diet and physical activity patterns in a population of community-dwelling seniors. This advice will be based on personal preference, genotype, phenotype and measures of personal muscle health status as well as socio-psychological factors. These data will be combined in decision trees leading to optimal, personalised advice that is expected to give higher compliance with positive effects on muscle health. Furthermore, the secondary objective of this pilot-study is to gain insight into the varation of different parameters of muscle health among community-dwelling seniors.

Study design

Single-blind randomised intervention study with a duration of 9 weeks

Intervention

Every three weeks, participants will receive advice on diet and physical activity patterns with personalised content and communicated in personalised form. Content of the advice will be personalised based on cut-off scores on personal health measures (i.e. parameters of metabolic health, genetic variation (SNP), nutrient intake, anthropometry, physical activity, patient specific complaints, quality of life and vitality) and the form will be modified based on socio-psychological factors (freedom of choice, self-efficacy and implementation intentions).

Study burden and risks

The risks associated with participation can be considered negligible and the burden can be considered minimal. There are no special risks for participation in this study. The included personal advices are based on personal

possibilities and do not pose any health risks. Subjects will not be supplied with an investigational product. The non-investigational product used (the PhenFlex challenge) is only used at baseline and at the end as a test method and is a safe food product. Therefore subjects are not exposed to additional risks.

Contacts

Public
TNO

Utrechtseweg 48
Zeist 3704 HE
NL
Scientific
TNO

Utrechtseweg 48
Zeist 3704 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, subjects must meet all of the following criteria:
* They have signed the informed consent
* They are * 60 years old
* They are considered healthy based on the 'Health and Lifestyle questionnaire'

(F1_1_screening questionnaire)
* They have a Body Mass Index of 20-30 kg/m2
* They perform sedentary behaviour for at least 10 hours per day
* They are able and willing to use self-monitoring devices
* They have a desktop or laptop with internet access at home

Exclusion criteria

Potential subjects who meet any of the following criteria will be excluded from participation in this study:
* They use medication known for its effects on blood glucose, cholesterol or insulin
* They have a history of medical or surgical events that may significantly affect the study outcome, including physical limitations, cardio-vascular events or cerebro vascular accident as assessed by the 'Health and Lifestyle questionnaire' (F1_1_screening questionnaire)
* They are rehabilitating
* They have a pacemaker
* They are currently suffering from diabetes type I or type II as determined by the general practitioner
* They follow a specific diet (e.g. slimming diet or medically prescribed diet)
* They have physical, mental or practical limitations in using computerized systems
* They have an alcohol consumption > 28 units/week for males and > 21 units (drinks)/week for females
* They experienced unintended weight loss or weight gain of > 2 kg in the three months prior to the screening
* They do not accept that the general practitioner will be informed about participation of the study
* They are away for a longer period of time during the intervention period

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Not approved

Date:	17-12-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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
CCMO	NL53218.081.15