Ecologically sustainable nutriton for older adults (55+) with obesity.

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

Summary

ID

NL-OMON53195

Source
ToetsingOnline

Brief title
2EAT

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Sarcopenic obesity; Loss of muscle mass in severely overweight

Health condition

Sarcopene obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Regieorgaan SIA - Praktijk gericht onderzoek (RAAK-PRO)

Intervention

Keyword: (Plant-based) Protein, Muscle health, Obesity, Sarcopenia

Outcome measures

Primary outcome

The main study parameter is the change in plant-based protein intake compared

to animal protein intake between baseline and three (primary) and six-months

intervention (3-day dietary record).

Secondary outcome

Weight loss;

Skeletal muscle mass;

Exploratory parameters:

Muscle strenth: hand grip strength

Physical performance: 400m walk test, short physical performance battery

Body composition: fat free mass, total body water, body weight, waist

circumference, BMI

Metabolic outcomes: blood pressure, heart rate, lipid profile, blood glucose

(HOMA-index), inflammation (CRP), nutritional status (vitamin B12 and

heamoglobin)

Quality of live

Vitality

Nutritional adequacy

Behavioral change

Process evaluation of the dietary treatment

Study description

Background summary

In the Netherlands, there is a high prevalence of obesity among older adults (55+) which is expected to rise in the coming years. Weight loss is crucial to improving health outcomes for older adults, but it also poses the risk of losing skeletal muscle mass. Therefore, dietetic advice for older obese clients should consider the exacerbated age-related loss of skeletal muscle mass and encourage the intake of extra proteins, alongside calorie restriction. Currently, dieticians typically suggest an increase in animal-based proteins due to their proven ability to stimulate muscle protein synthesis. On average 60% of the protein intake in the Netherlands is of animal-based sources. However, animal-based proteins have a high ecological impact, while plant-based proteins have a lower impact and offer numerous health benefits. To address this, we developed a new dietary concept that aligns with current dietary guidelines for older adults (55+) with obesity, incorporating a calorie restriction and protein enrichment (towards 1.2 g/kg/d, minimum of 0.8 g/kg/d), of which >=60% (minimum of 50%) (compared to current 40%) is plant-based proteins and providing all essential amino acids.

Study objective

Our primary objective of the feasibility study is to assess the acceptability and feasibility of the developed 2EAT dietary treatment in older adults with obesity.

The primary objective the main study (RCT) is to investigate whether a shift towards more plant-based (>=60%) protein intake can be achieved in a calorie restricted diet for three (primary) and six months in older adults (55+) with obesity.

The secondary objectives of the study are to assess the effects of the 2EAT dietary treatment on weight loss and skeletal muscle mass.

The exploratory objectives of the study are to assess the effect of the 2EAT dietary treatment on physical health outcomes: muscle strength and physical performance; body composition; metabolic bloodparameters; vitality and quality

of life; nutritional intake; behavioral changes; process of dietary treatment.

Study design

The study consists of two phases. In phase 1, a feasibility study will evaluate the acceptability and feasibility of the 2EAT dietary treatment in older adults with obesity. In phase 2, a randomized controlled trial of 6 months with two parallel intervention groups will be conducted to investigate the effect of the 2EAT diet (>=60% plant-based protein) over time.

Intervention

The 2EAT dietary intervention includes dietary counselling focussed on behavioural change, and a diet with an energy restriction of 500 kcal and increased protein intake based towards 1.2 g/kg/day (minimum of 0.8 g/kg/d), of which >=60% (minimum of 50%) is plant-based. In the randomized controlled trial, half of the participants will be randomized to the control dietary treatment (40% plant-based protein).

Study burden and risks

The risks associated with participation are minimal. Assessments will be carried out in a private controlled setting and interventions are guided by trained dieticians and researchers. Participation in this study should benefit older adults by improving body composition, providing social aspects and personal health insights. The results of this trial will be used to support evidence-based practice for more environmentally sustainable dietetic practice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Aged 55 or older
Are obese: have a BMI of >30 kg/m2 or BMI >27 kg/m2 and waist circumference >88 cm (women) or >102 cm (men)
Living independently (not in a health facility)
The willingness that the general practitioner will be notified of study participation
Written informed consent
Willingness to comply with the protocol
Consent of the study physician

Exclusion criteria

Inability to understand the Dutch language
Cognitive impairment (MMSE <15)
Use of total or partial parenteral nutrition (TPN)
Alcohol or drug abuse in the opinion of the investigator
Current enrolment in a fixed rehabilitation program or other intervention studies
Palliative treatment or a life expectancy of <= 3 months
Following a vegetarian or vegan (100% plant-based) diet
Bariatric surgery;
Active medical treatment interfering with this intervention (e.g. weight loss medication such as Ozempic cancer patients receiving systemic and immune therapy)
Physical disabled: unable to meet the general daily exercise guideline for adults (24)
Planned a holiday during the intervention period and is unable to attend group-

or individual sessions for > 1 week (in phase 1) or > 3 weeks (in phase 2)

The health conditions below will be assessed by the study physician. When a condition interferes the dietary treatment or if the diet worsens the participants health it counts as exclusion criteria:
Diagnosed with unstable coronary heart disease (CHD), decompensated heart failure, uncontrolled hypertension or uncontrolled arrhythmias (e.g. heart failure NYHA >3)
Diagnosed degenerative neurocognitive disorders
Diagnosed with renal failure
COPD GOLD >3

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2024
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	04-12-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	03-04-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL84358.018.23