ENRICHED

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To compare the effect of a 6-month of enriched care consisting of additional protein intake and regular resistance exercise on the prevalence of disproportional fat-free mass loss (defined as a FFML/WL>30% as main outcome parameter) in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57119

Source
ToetsingOnline

Brief title
ENRICHED

Condition

- Gastrointestinal therapeutic procedures
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Disproportional fat-free mass loss, metabolic bariatric surgery, protein supplementation, resistance excercise

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

- Life style intervention
- Movement therapy
- Food (substances)

Keyword: Disproportional fat-free mass loss, Metabolic bariatric surgery, Protien supplementation, Resistance exercise

Explanation

N.a.

Outcome measures

Primary outcome

Our primary outcome is the prevalence of disproportional FFM loss, defined as FFML/WL>30%. Changes in body composition, such as FFM loss and weight loss (WL) are determined by bioelectrical impedance analysis (BIA) in the total population (N=400); and by Dual Energy X-ray Absorptiometry (DXA) in a subgroup (n=100).

Secondary outcome

Secondary outcomes are body composition, (cardio)metabolic health, muscle strength, muscle function, cardiorespiratory fitness and health-related quality of life, and healthcare consumption.

Study description

Background summary

There is a worldwide increase in both prevalence and severity of obesity with currently over 153,000 individuals with severe obesity (i.e., body mass index >40 kg/m2) in the Netherlands. Obesity is a chronic disease and a risk factor for cardiovascular disease, type 2 diabetes mellitus and various cancers and negatively impacts both physical and psychological aspects of quality of life. For these individuals, metabolic-bariatric surgery (MBS) is the most effective approach to achieve long-term weight loss and substantial reduction in comorbidities. Therefore, the number of patients undergoing MBS has exponentially increased up to 12,000 procedures annually in the Netherlands. Previous studies have repeatedly shown that MBS is a cost-effective procedure in terms of disease prevention and related future health care costs. However, long-term health in these patients clearly leaves room for improvement.

Post-MBS weight loss consists of both fat mass (FM) and fat-free mass (FFM). Skeletal muscle tissue is the largest component of FFM and is essential for functional capacity, metabolic health, thermoregulation and bone strength. Excessive FM and insufficient FFM, i.e. sarcopenic obesity, have negative health consequences, therefore optimal weight loss strives for FFM maintenance while maximizing FM loss. Our research group showed that the ratio between FM loss and FFM loss varies largely between patients who underwent MBS, with an average percentage of FFM loss of total weight loss (=FFML/WL) of 20-25% [range 6-54%] at 12 months post-surgery. Our recent data showed that a FFML/WL>=25% was associated with a 1.56 times higher risk for major adverse cardiovascular events and all-cause mortality in middle-aged and older patients. This study highlights that a disproportional composition of weight loss with a relatively high FFM loss could be detrimental for future health. Furthermore, 28-34% of the patients showed a FFML/WL>=25%, underscoring that disproportional FFML/WL is highly prevalent among individuals who underwent MBS. Therefore, MBS care should strive for a more balanced weight loss and strategies that counteract FFM loss during MBS-induced weight loss are required, thereby also improving metabolic health.

Interventions with additional protein and resistance exercise are successful in increasing or maintaining muscle mass in other clinical populations. However, studies that examined the impact of additional protein and exercise on FFM in patients who underwent MBS remain inconclusive, presumably due to feasibility issues. Feasibility issues may arise from impaired protein intake, digestion and absorption following the alterations to the gastro-intestinal tract, and/or population-specific barriers towards exercise and diet. These population-specific limitations should be incorporated into new, feasible intervention protocols.

Study objective

To compare the effect of a 6-month of enriched care consisting of additional protein intake and regular resistance exercise on the prevalence of disproportional fat-free mass loss (defined as a FFML/WL>30% as main outcome parameter) in patients who underwent MBS compared to standard care.

Study design

This is a multicenter randomized controlled trial that includes three clinical centers of the Nederlandse Obesitas Kliniek (NOK, Dutch Obesity Clinic). In each center study participants will be allocated to either the control group (standard care) or intervention group (enriched care). Participants and researchers could not be blinded due to practical considerations. Patients will be informed and recruited during the preoperative care program. An initial screening is performed by the standard care team. Researchers can determine eligibility based on in- and exclusion criteria. Informed consent will be collected prior to any measurements.

Intervention

During the 6-month intervention period, the control group follows standard care protocols,

while standard care is complemented by additional protein intake, resistance training and counseling sessions with dieticians and movement experts for the enriched care group. Patients in the enriched care group will postoperatively be provided with powdered whey protein supplements during twelve weeks. To enhance tolerability and, consequently, compliance, patients are instructed to follow a gradually increasing protein supplementation protocol. This protocol includes 15-20 grams of whey supplementation daily for 4 weeks, followed by 15-20 grams twice daily for the next 4 weeks, and finally 15-20 grams thrice daily for an additional 4 weeks. After twelve weeks, a transition from protein supplements to protein-rich food products into the daily intake pattern is made. Counseling sessions with dieticians are offered during the intervention periode to support participants with the dietary adjustments.

Furthermore, participants in the intervention group will be invited to join supervised group sessions of resistance exercise at their NOK center once a week. Next to these sessions, patients are instructed to perform resistance exercises in their home environment 2-3 times a week. They will be guided through this process with the help of sessions with a movement expert.

Given the gastrointestinal and physical limitations postoperatively, the protein and resistance training interventions will commence three weeks after the surgical procedure. After the intervention period, all patients are assigned to standard care.

Measurements are performed before MBS, and 3-, 6-, and 12-months after MBS.

Study burden and risks

The risks involved in this study are minimal. The protein supplements provided are generally available products, which are produced according to the HACCP/ISO22000 regulations in certified facilities and using approved and commercially available ingredients. Resistance training is performed with regular supervision of trained movement experts and adjusted to the participant’s needs and ability. Measures related to this study are blood samples, body composition analysis, muscle strength/function tests, submaximal exercise tests, physical activity and dietary intake assessments and questionnaires/diaries. These measures are minimally invasive and can be graded as ‘negligible risk’. Burden of this study is mainly attributed to a greater time investment than during their standard care program. On the other hand, participants in the enriched care group may benefit from improved composition of weight loss and greater improvements in secondary outcomes.

Contacts

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Trial sites

Trial sites in the Netherlands

Nederlandse Obesitas Kliniek - Locatie Nieuwegein
Target size: 200

Nederlandse Obesitas Kliniek - Locatie West
Target size: 200

Amsterdam UMC
Target size: 0

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- A scheduled metabolic bariatric surgery procedure (i.e., a RYGB or sleeve gastrectomy)
- Participation in the NOK care program
- Able to understand and perform the study procedures

Exclusion criteria

- Allergic or sensitive for milk proteins, or lactose intolerant
- Diagnosed renal insufficiency
- Diagnosed intestinal diseases influencing the uptake of protein (i.e., active inflammatory bowel disease, Crohn's disease)
- Inability to perform any resistance training exercises (e.g., severe physical limitations)
- Inability to comprehend scheduled procedures (e.g., language barriers)

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2025
Enrollment:	400
Duration:	14 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	26-11-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-04-2025
Application type:	Amendment
Review commission:	METC Oost-Nederland

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	NL87367.091.24
Research portal	NL-005570