Direct measurement of changes in food intake behaviour in obese women after bariatric surgery or lifestyle intervention

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To assess changes in food intake and food preference (e.g., fat and sugar) after bariatric surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49513

Source
ToetsingOnline

Brief title
CIBuS

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
morbid obesity, overweight

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,eigen middelen

Intervention

Keyword: Bariatric surgery, Eating behaviour, Food intake, Obesity

Outcome measures

Primary outcome

Primary: Changes in caloric intake from sugar and fat for the bariatric surgery groups compared to the lifestyle group before and after treatment.

Secondary outcome

Changes in cumulative caloric intake as well as changes in cumulative caloric intake from all macronutrients (carbohydrates, including sugar, fat and protein) for each group over time.

Differences in caloric intake will be correlated with % weight loss at one year after the surgery or lifestyle intervention.

Aditionally, drinking microstructure over time will be assessed and we will make comparisons between groups.

Changes in food preference in each group over time for sweetness and fattiness obtained from questionnaire, compared with the Drinkometer results.

Study description

Background summary

Bariatric surgery is the most effective long-term strategy to reduce weight and maintain weight loss in patients with morbid obesity. Changes in diet selection have been implicated as an important candidate mechanism. Patients prefer

low-sugar low-fat food and generally report finding food less enjoyable after bariatric surgery when compared to preoperatively. However, the empirical support for this is controversial and largely based on indirect measures such as self-reported food intake data which has been shown to be prone to inaccuracy due to its subjective character. Therefore, the interaction of bariatric surgery and food choice remains to be tested with direct measures of dietary intake and eating behaviour. We aim to use a direct microstructural analysis of food preference to test the hypothesis that bariatric surgery decreases relative caloric intake of stimuli with high-fat/ high-sucrose content in favour of stimuli lower in fat and sucrose content without fundamentally modulating the palatability of these foods and fluids. Bariatric patients will be compared to a lifestyle intervention group to compare the effect of surgery and lifestyle advice on changes in intake behaviour.

Study objective

To assess changes in food intake and food preference (e.g., fat and sugar) after bariatric surgery.

Study design

Prospective observational study of patients before and after bariatric surgery or combined lifestyle intervention. Patients will attend 5 drinkometer tests, one time before surgery or lifestyle intervention and 4 times during the first year of follow-up. With the drinkometer test patients get four types of drinks, varying in sugar and fat content.

Study burden and risks

The measurements are non-invasive and carry minimal risk. Moreover, the measurements will be combined with the regular follow-up visits as much as possible, patients only will have no extra visits to the outpatient clinic. The study is non-therapeutic.

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

- Woman
- Age between 18 and 67 years of age (standard for eligibility for bariatric surgery)
- Patients must be able to adhere to the study visit schedule
- Independently mobile
- Patients must be able to give informed consent (IC) prior to any study procedures
- Surgical (1) and non-surgical (2) groups:
1. Eligible for bariatric surgery (BMI > 35 kg/m2 and clinically indicated bariatric surgery operation in agreement with the IFSO criteria)
2. Patients with a BMI of 30-40 kg/m2, who are planning to join the COOL-lifestyle program

Exclusion criteria

• Pre-operatively/lifestyle group: Factors impairing ability to consume meal such as
o Significant dysphagia
o Gastric outlet obstruction
o Anything factor that prevents subjects from drinking or eating a meal
• Post-operatively: Factors impairing ability to consume meal such as

o Significant and persistent surgical complications or
o Anything that prevents subjects from drinking or eating a meal.
• Systemic or gastrointestinal condition which may affect food intake or preference (including diabetes mellitus)
• Pregnancy or lactation, or planning to get pregnant during the study period
• Patients who have an intolerance or allergy for one of the components of the test product
(e.g. lactose)
• Active and significant psychiatric illness including substance misuse
• Significant cognitive or communication issues
• Medications with documented effect on food intake or food preference
• Participating in another scientific study at the same time, if study procedures of one of the
studies may affect the outcome in the other study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2021
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2020

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL73537.091.20