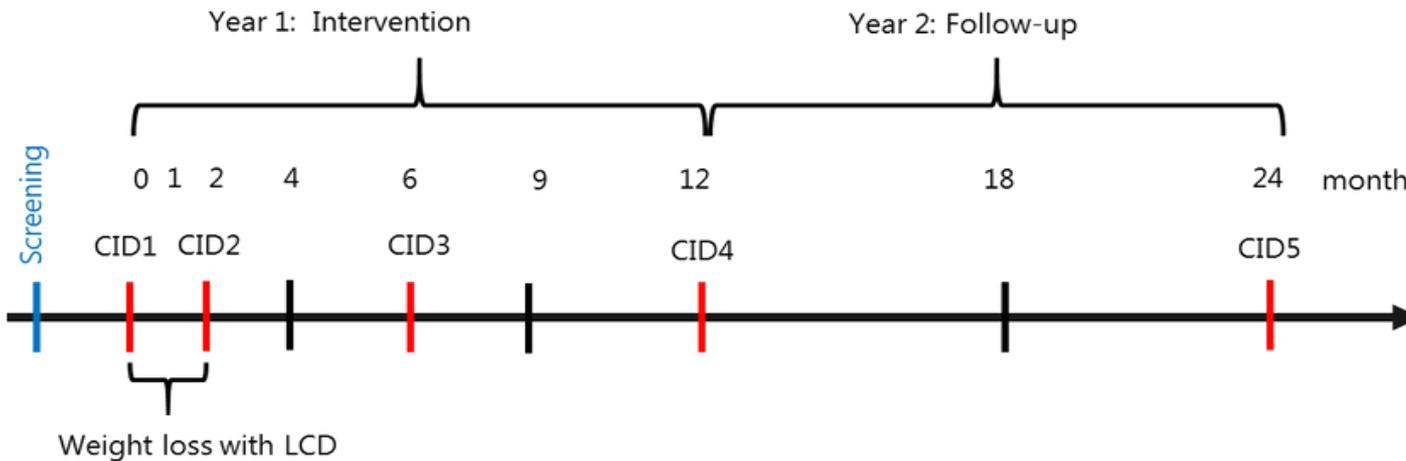


WP3

Long-term clinical trial

SWEET



N=660 participants in total (330 adults & children) (n ~ 165/centre) 4 clinical trial centres:

- University of Copenhagen, DK (lead) – Anne Raben
University of Harokopio, GR (co-lead) – Yannis Mannios
- University of Maastricht, NL – Ellen Blaak
University of Navarra, ES – J. Alfredo Martinez



WP3

Objective and endpoints

SWEET 

Primary objective :

To investigate the efficacy and safety of combined and prolonged use of S&SEs - as part of a healthy diet - in a population with overweight or obesity.

Co-primary endpoints:

Efficacy: Change in BW. Safety: Change in microbiota.

Secondary end-points :

Efficacy: Changes in anthropometry

Risk factors for diabetes and cardiovascular disease

Gut-brain signaling molecules.

Safety : Changes in markers of allergenicity, liver fat, adverse events, and concomitant medication.

Further: Subjective neuro-behaviour (eg food preferences, perception of sweeteners).

Subjective appetite sensations, food reward, craving.

Underlying physiological and psychological drivers.



WP3

Study design



Figure 1. Study design of the RCT

Treat ment arms	Year 1 – Intervention Rapid weight loss + weight maintenance With supervision		Year 2 – Follow-up Weight maintenance No supervision
Arm 1	LCD 2 months Adults only	Healthy diet < 10 E% sugar 10 months S&SE's allowed	Healthy diet < 10 E% sugar 12 months S&SE's allowed
Arm 2	LCD 2 months Adults only	Healthy diet < 10 E% sugar 10 months No S&SEs allowed	Healthy diet < 10 E% sugar 12 months No S&SEs allowed

E%: Energy-percent. LCD: Low calorie diet.



WP3

SWEET 

Participants:

Families with at least:

- One parent with overweight or obesity (BMI ≥ 25 kg/m², 18-65 y, both gender) and one healthy overweight child (BMI-for-age > 85th percentile, targeting 6-12 y)
- In total 660 participants; at least 330 adults (165 for each arm) + 330 children
- **165** participants per centre

Intervention:

Adults

All: Standard dietary recommendations for weight management. Achieve recommended < 10 E% sugar.

I) Without inclusion of S&SEs in the diet

II) With specific advice on inclusion of S&SE enriched products (Incorporation of S&SEs to replace sugar)

Diets will be “self-purchase”, with some centres having selected available products.

During y 1, families will receive dietary advice (e.g. supervised by dietician) at baseline and in months 1, 2, 4, 6, 9 and 12. Only 1 supervision during year 2.

*Children: Recommendations of the American Academy of Pediatrics on prevention, assessment and treatment of overweight and obesity will be used.

