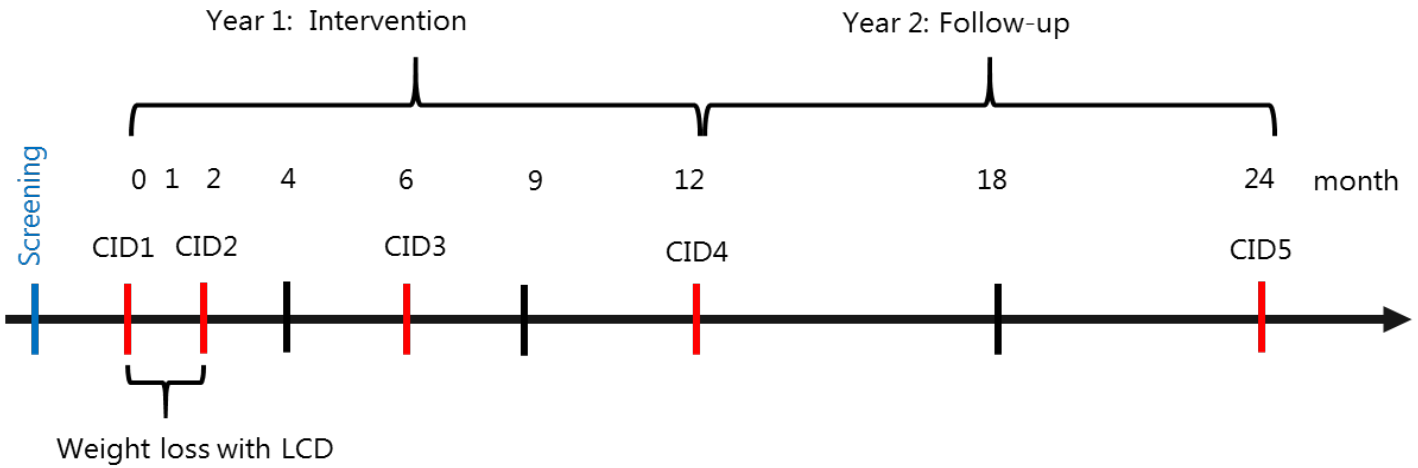
WP3
Long-term clinical trial



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

Co-funded by the Horizon 2020 programme of the European Union

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Objective and endpoints

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 of overweight/obese adults and children.

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.

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Study design

Figure 1. Study design of the RCT

Treatment 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.

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Participants:

Families with at least:

- One overweight or obese parent (BMI ≥25 kg/m^2, 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 advise (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 de used.

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